Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016 K101128

MAY 26 2011

5 510(k) Summary

5.1 Applicant and Correspondent

Name:	Filligent (HK) Limited
Address:	7th Floor, 69 Jervois Street Sheung Wan Hong Kong
Contact Person:	Melissa Mowbray-d'Arbela Chief Executive Officer
Phone:	(852) 2542 2400
Date of Preparation:	March 11, 2011

5.2 Manufacturer

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

5.3 Name of Device

Trade/Proprietary/Model Name: BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A
Premium BF-200-3013A

Common Name:	Surgical Facemask
Classification Name:	Mask, Surgical
Classification Regulation:	878.4040
Panel:	General Hospital
Product Code:	OUK
Recognized Performance Std:	ASTM F2100-07 (refer to submission)

5.4 Devices to Which New Device is Substantially Equivalent

Device Name:	Prestige Ameritech Face Mask
Manufacturer:	Prestige Ameritech
Reference:	K061716

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.5 Device Description

The BioFriend™ BioMask™ surgical facemask is offered in two mask styles, Model: BF-200-2001A ("Universal") and Model: BF-200-3013A ("Premium"). The Universal model is a standard flat mask with pleats, while the Premium model is flat-folded and expands into a convex-shaped mask. The Premium model also has ear adjusters and an anti-fog nose flap. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in these devices are typical construction materials commonly used in surgical facemasks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second inner layer is treated with copper and zinc. Both layers inactivate influenza viruses using different mechanisms of action. Masks are held in place on the wearer with elastic loops and contain a malleable metal nosepiece strip.

5.6 Statement of Intended Use

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks inactivate 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

There are two models: (1) Universal (BF-200-2001A) - is a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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5.7 Summary of Technological Characteristics

The BioFriend™ BioMask™ surgical facemasks have substantially equivalent filter and barrier properties as the predicate device, and conform to the recognized FDA consensus standard ASTM F2100-07 Standard Specification for Performance of Materials used in Medical Face Masks. Both models of the BioFriend™ BioMask™ surgical facemask are constructed from the same materials and layers, and are identical in all respects other than shape. The outer layer of both models is coated with a hydrophilic plastic that allows aerosolized droplets contacting the surface of the mask to be rapidly absorbed into the inner layers. Both the outer and second inner layers are treated with different compounds that independently inactivate viruses through different mechanisms of action. Laboratory *(in vitro)* test results demonstrate that the BioFriend™ BioMask™ surgical facemasks inactivate 99.99% (≥4-logs) of 15 different strains of Influenza A and B viruses, including the circulating 2009 pandemic H1N1, recent vaccine isolates, major reassortments and avian, swine and equine isolates after 5 minutes contact with the mask surface.

The BioFriend™ BioMask™ surgical facemasks have been tested for, and appropriately passed standardized tests for, fluid penetration resistance, particulate filtration efficiency, bacterial filtration efficiency, flammability, and breathing resistance. The device as a whole has been shown to be biocompatible through standardized tests for irritation, sensitization and extractables.

The materials of construction used in the BioFriend™ BioMask™ surgical facemasks are equivalent to those of the predicate device. The devices as a whole are substantially equivalent to the predicate device.

5.8 Brief description of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

- Bacterial Filtration Efficiency – ASTM F2101
- Sub-micron Particulate Filtration Efficiency – ASTM F2299
- Fluid Penetration Resistance – ASTM F1862
- Breathing Resistance – MIL-M-3654C
- Flammability Testing – 16 CFR 1610
- Biocompatibility, Irritation – ISO 10993-10
- Biocompatibility, Sensitization – ISO 10993-10
- Biocompatibility, Chemical Characterization – ISO 10993-18

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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5.9 Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Not applicable.

5.10 Conclusions drawn from the nonclinical and clinical tests

Standardized testing has shown that the construction materials used in both models of the BioFriend™ BioMask™ surgical facemask are substantially equivalent to those of the predicate device. The devices as a whole have been demonstrated to be biocompatible through irritation and sensitization testing, with toxicological assessment of the devices' components which could potentially be released with inhalation or salivary contact, indicating the devices are safe for use in the intended application. Laboratory testing has demonstrated the devices' efficacy. Both models of the BioFriend™ BioMask™ surgical facemask have been shown to be substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Filligent (HK) Limited
C/O Mr. Ian Gordon
Emergo Group, Incorporated
611 West 5th Street Third Floor
Austin, Texas 78701

MAY 26 2011

Re: K101128
Trade/Device Name: BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: OUK
Dated: May 20, 2011
Received: May 23, 2011

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

4 Indications for Use Statement

510(k) Number:

K101128.

Device Name:

BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A

Indications for Use:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks inactivate 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007,A/Wisconsin/67/2005,), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

Prescription Use _____ (21 CFR 801 Subpart D) AND/OR Over-The Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K101128

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded and expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of microorganisms, body fluids and particulate material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 04, 2011

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY
SUITE 500
AUSTIN, TEXAS 78746
ATTN: IAN GORDON

510k Number: K101128

Product: BIOFRIEND BIOMASK SURGICAL FAC

Extended Until: 05/19/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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filligent
creating
global health choices

April 1, 2011

FDA CDRH DMC
APR - 4 2011
Received

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Request for Extension of Time to Respond to Additional Information Request

510(k) Premarket Notification – K101128

Filligent (HK) Limited ("Filligent") respectfully asks for an extension of time to respond to the official FDA letter, dated March 8, 2011, placing on hold our 510(k) Premarket Notification pending receipt of the additional information requested by the Office of Device Evaluation, by fax on March 7, 2011.

Filligent respectfully requests an additional forty-five (45) days, from the date hereof, to respond to the FDA's request for additional information.

Should you require additional information as to this, please do not hesitate to contact us at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely,

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH-CDE/DMC at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent

K101128/A001

May 4, 2010

FDA CDRH DMC 438

MAY - 6 2010

Received

Document Mail Center – WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr Murphey

Re: Supplement to 510(k) Premarket Notification – K101128

Our firm has submitted a 510(k) premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128). On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Infection Control Devices Branch, was received requesting Filligent to provide further information.

The enclosed submission is a response to such request and constitutes a supplement to the 510(k) Premarket Notification – K101128.

Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

May 4, 2010

Document Mail Center – WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr Murphey

Re: Supplement to 510(k) Premarket Notification – K101128

Our firm has submitted a 510(k) premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128). On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Infection Control Devices Branch, was received requesting Filligent to provide further information.

The enclosed submission is a response to such request and constitutes a supplement to the 510(k) Premarket Notification – K101128.

Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Supplementary Response to FDA Request

Our firm has submitted a premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128, the "510(k) Submission"). On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Infection Control Devices Branch, was received requesting Filligent to provide further information:

As we review your 510(k) submission, it is very important that we have a complete description of the antimicrobial agents in the Filligent BioMasks and how they interact with each other and their safety for wearers of the devices. Please provide the following information, either with respect to its current location in the file or as additional information (we have looked for these items and could not find them):

1. The MEC (minimum effective concentration) of the antimicrobial agents in your device - citric acid, copper, zinc. If you believe that (b)(4) [redacted] *contribute to the antimicrobial activity, please include them as well.*

2. The acceptance criteria for the pH of the outer layer of your devices

3. The pH of the second layer of your devices when the aerosols contacting the outer layer are "drawn into" the second layer

4. The acceptance criteria for the levels of citric acid, copper and zinc in your devices

5. The MSDS sheets for citric acid, (b)(4) [redacted]

6. Please provide the levels of citric acid, copper and zinc in your devices by ugm or mgm per unit of area such as cm2 for your devices

7. Please provide the total amounts of citric acid, copper and zinc per total, complete device for each of your mask models

8. Please provide the dimensions and area for each of your two mask models

9. Please identify the contribution of (b)(4) [redacted] *to the antimicrobial activity of your device*

10. Please state whether or not any "anti-fog" compound has been added to the polyurethane nose sponge on the Premium BF 200-3013 mask or where it is the presence of untreated polyurethane which is considered to provide the anti-fog function

If the above information is not already in the file, please provide it to Mr. Elliott and to me electronically as soon as you can. Please also send a copy of this material to the Document mail Center so that it can be officially added to the contents of your file.

We may have additional questions later as we proceed with this review. If that is the case, we will send them to you. We expect to request consultation from the Center for Drug Evaluation and Research (CDER) on this interesting submission. However, we must be sure before we place the request that all of the information which CDER will need will be available in the file. If you have any questions about the information needed, please let me know.

Thank you very much for your assistance in providing this information.

Regards,
Sheila A. Murphey, MD

* *

1. The MEC (minimum effective concentration) of the antimicrobial agents in your device - citric acid, copper, zinc. If you believe that (b)(4) [redacted] **contribute to the antimicrobial activity, please include them as well**.

Questions 1 to 3 will be addressed in a subsequent written response to the FDA on or about May 21, 2010. Additional MEC GLP testing has been initiated by Filligent with Microbiotest Inc. Salt Lake City, Utah to supplement internal test data characterizing the antimicrobial agents in the BioMask. Preliminary test data is expected May 12, 2010 with audited GLP reports on May 21, 2010. A complete response on these issues will be made to the FDA at that time.

2. The acceptance criteria for the pH of the outer layer of your devices

See response to Question 1.

3. The pH of the second layer of your devices when the aerosols contacting the outer layer are "drawn into" the second layer

See response to Question 1.

(b)(4) [redacted]

5. The MSDS sheets for (b)(4) [redacted]

(b)(4)

[redacted]

The MSDS sheets for the remaining chemical constituents of the BioFriend™ BioMask™ are provided in Appendix 2:

(b)(4)

[redacted]

6. Please provide the levels of citric acid, copper and zinc in your devices by ugm or mgm per unit of area such as cm^2 for your devices

See response to Question 7.

7. Please provide the total amounts of citric acid, copper and zinc per total, complete device for each of your mask models

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical face masks and are being

used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second layer is treated with copper and zinc. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip. One model is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard "comfort" features such ear adjusters and an anti-fog nose insert. The materials used in the construction of the Universal BF-200-2001 and Premium BF-200-3013 are of approximately the same total surface area, [redacted] respectively (Table 2). The composition of the antimicrobial agents contained in the BioFriend™ BioMask™ surgical facemasks, is summarized in Table 1, and is based on an average surface area of [redacted] (also refer to Tables 15-4 and 15-5, page 15-4 of the 510(k) Submission). The minimum and maximum levels of the antimicrobial agents in the devices, as defined by the acceptance criteria, are also given.

(b)(4)

[redacted]

[1] Based on average total surface area of [redacted]
[2] min and max as calculated from the acceptance criteria

8. Please provide the dimensions and area for each of your two mask models

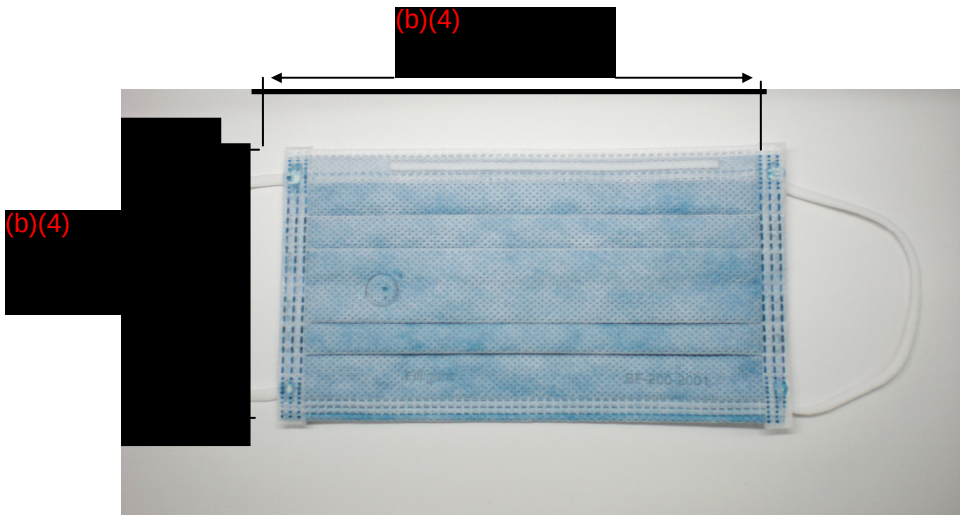
Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. One is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard "comfort" features such

ear adjusters and an anti-fog nose insert. The major dimensions for each device are summarized in Table 2, and Figures 1 and 2. Both the Universal BF-200-2001 and Premium BF-200-3013 contain approximately the same total surface area of material of ~288 cm^2 (also refer to Table 15-5, page 15-4 of 510(k) submission).

(b)(4)

[redacted]

Figure 1 Major Dimensions of the BioFriend™ BioMask™ Universal BF-200-2001



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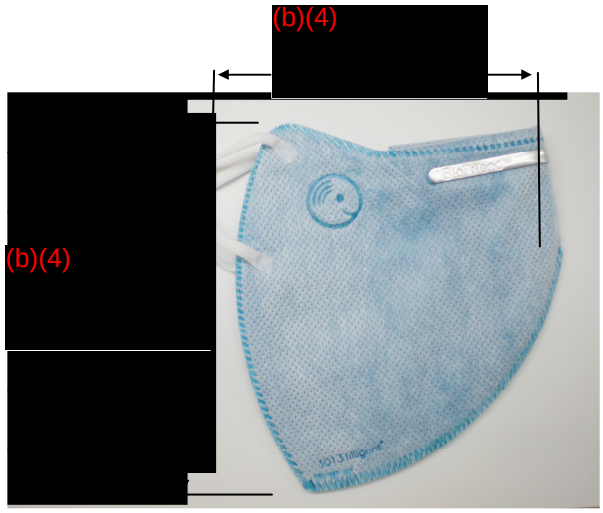
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Figure 2 Major Dimensions of the BioFriend™ BioMask™ Premium BF-200-3013



(b)(4)

[redacted]

10. Please state whether or not any "anti-fog" compound has been added to the polyurethane nose sponge on the Premium BF 200-3013 mask or where it is the presence of untreated polyurethane which is considered to provide the anti-fog function

No “anti-fog” compounds have been added to the polyurethane sponge. The presence of untreated polyurethane on the inside of the nose-flap is used to improve seal of the nose-flap around the nose to help prevent glasses and face shields from fogging.

[1] Lawton, E. A. (1958) The thermal stability of copper phthalocyanine. *J. Phys. Chem.*62 (3): 384

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Appendix 1

Contents

A MSDS data for Citric Acid, Science Lab, 14025 Smith Rd., Houston Texas 77396, November 6, 2008. S1-9

(b)(4)

[redacted]

Appendix 2

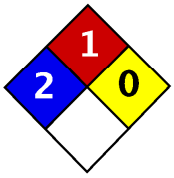
Contents

A MSDS data for Polyvinyl Alcohol, Science Lab, 14025 Smith Rd., Houston Texas 77396, November 6, 2008. S1-28

(b)(4)

[redacted]

Appendix 1-A: Citric Acid MSDS



Health	2
Fire	1
Reactivity	0
Personal Protection	E

Material Safety Data Sheet
Citric acid MSDS

Section 1: Chemical Product and Company Identification

Product Name: Citric acid

Catalog Codes: SLC5449, SLC2665, SLC4453, SLC1660, SLC3451

CAS#: 77-92-9

RTECS: GE7350000

TSCA: TSCA 8(b) inventory: Citric acid

CI#: Not available.

Synonym: 2-Hydroxy-1,2,3-propanetricarboxylic acid

Chemical Name: Citric Acid

Chemical Formula: C6H8O7

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Citric acid	77-92-9	100

Toxicological Data on Ingredients: Citric acid: ORAL (LD50): Acute: 5040 mg/kg [Mouse]. 3000 mg/kg [Rat].

Section 3: Hazards Identification

Potential Acute Health Effects:
Hazardous in case of eye contact (irritant), of inhalation (lung irritant). Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion. The amount of tissue damage depends on length of contact. Eye contact can result in corneal damage or blindness. Skin contact can produce inflammation and blistering. Severe over-exposure can produce lung damage, choking, unconsciousness or death.

Potential Chronic Health Effects:
Slightly hazardous in case of skin contact (sensitizer).
CARCINOGENIC EFFECTS: Not available.
MUTAGENIC EFFECTS: Not available.
TERATOGENIC EFFECTS: Not available.
DEVELOPMENTAL TOXICITY: Not available.
The substance may be toxic to teeth.
Repeated or prolonged exposure to the substance can produce target organs damage. Repeated exposure of the

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Appendix 1-A: Citric Acid MSDS

eyes to a low level of dust can produce eye irritation. Repeated skin exposure can produce local skin destruction, or dermatitis. Repeated inhalation of dust can produce varying degree of respiratory irritation or lung damage.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Skin Contact:
In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact:
Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: 1010°C (1850°F)

Flash Points: Not available.

Flammable Limits: LOWER: 0.28 Kg/M3 (Dust) UPPER: 2.29 Kg/M3 (Dust)

Products of Combustion: These products are carbon oxides (CO, CO2).

Fire Hazards in Presence of Various Substances:
Slightly flammable to flammable in presence of heat.
Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Slightly explosive in presence of open flames and sparks.
Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Appendix 1-A: Citric Acid MSDS

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Eliminate all ignition sources. Call for assistance on disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, reducing agents, metals, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:
Safety glasses. Lab coat. Gloves (impervious). Dust respirator. Be sure to use an approved/certified respirator or equivalent. The dust respirator should be used for conditions where exposure has exceeded recommended exposure limits, dust is apparent, and engineering controls(adequate ventilation) are not feasible.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:
No exposure guidelines have been established.
ACGIH, NIOSH and OSHA have not developed exposure limits for this product.
The exposure limits given below are for particulates not otherwise classified:
ACGIH: 10 mg/m3 TWA (Total Inhalable fraction); 3 mg/m3 TWA (Respirable fraction)
OSHA: 15 mg/m3 TWA (Total dust); 5 mg/m3 TWA (Respirable Fraction)

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Crystalline powde)

Odor: Odorless.

Taste: Acid. (Strong.)

Molecular Weight: 192.13 g/mole

Color: Not available.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Appendix 1-A: Citric Acid

pH (1% soln/water): Not available.

Boiling Point: Decomposes.

Melting Point: 153°C (307.4°F)

Critical Temperature: Not available.

Specific Gravity: 1.665 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: The product is more soluble in water; log(oil/water) = -1.7

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water, diethyl ether.

Solubility:
Soluble in cold water, hot water, diethyl ether.
Insoluble in benzene.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents, reducing agents, metals, alkalis.

Corrosivity:
Corrosive in presence of aluminum, of zinc, of copper.
Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Incompatible with oxidizing agents, potassium tartrate, alkali, alkaline earth carbonates and bicarbonates, acetates, and sulfides, metal nitrates

Special Remarks on Corrosivity: Will corrode copper, zinc, aluminum and their alloys.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 3000 mg/kg [Rat].

Chronic Effects on Humans: May cause damage to the following organs: teeth.

Other Toxic Effects on Humans:

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Appendix 1-A: Citric Acid

Hazardous in case of inhalation (lung irritant).
Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion.

Special Remarks on Toxicity to Animals: LDL[Rabbit] - Route: oral; Dose: 7000mg/kg

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects:
Skin: Causes mild to moderate skin irritation. May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material.
Eyes: Causes moderate to severe eye irritation and possible injury.
Ingestion: May cause gastrointestinal (digestive) tract irritation with nausea, vomiting, diarrhea. Excessive intake may cause erosion of teeth and hypocalcemia (calcium deficiency in blood). May affect behavior/central nervous system (tremor, convulsions, muscle contraction or spasticity).
Inhalation: Causes moderate respiratory tract and mucous membrane irritation.
Chronic Potential Health Effects:
Frequent intake of citrated beverages may cause erosion of dental enamel and irritation of mucous membranes.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Citric acid

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): CLASS E: Corrosive solid.

DSCL (EEC):

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Appendix 1-A: Citric Acid

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

R36/37/38- Irritating to eyes, respiratory system and skin.
S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S37/39- Wear suitable gloves and eye/face protection.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: e

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves (impervious).
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.
Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 04:56 PM

Last Updated: 11/06/2008 12:00 PM

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Potential Health Effects

Inhalation:
Causes irritation to respiratory tract, symptoms may include coughing, sore throat, and shortness of breath. May result in ulceration and perforation of respiratory tract. When heated, this compound may give off copper fume, which can cause symptoms similar to the common cold, including chills and stuffiness of the head.
Ingestion:
May cause burning pain in the mouth, esophagus, and stomach. Hemorrhagic gastritis, nausea, vomiting, abdominal pain, metallic taste, and diarrhea may occur. If vomiting does not occur immediately systemic copper poisoning may occur. Symptoms may include capillary damage, headache, cold sweat, weak pulse, kidney and liver damage, central nervous excitation followed by depression, jaundice, convulsions, blood effects, paralysis and coma. Death may occur from shock or renal failure.
Skin Contact:
May cause irritation with redness and pain.
Eye Contact:
Corrosive. May cause irritation, redness, pain, blurred vision, discoloration, and damage.
Chronic Exposure:
Prolonged or repeated skin exposure may cause dermatitis. Prolonged or repeated exposure to dusts of copper salts may cause discoloration of the skin or hair, blood and liver damage, ulceration and perforation of the nasal septum, runny nose, metallic taste, and atrophic changes and irritation of the mucous membranes.
Aggravation of Pre-existing Conditions:
Persons with pre-existing skin disorders, impaired liver, kidney, or pulmonary function, glucose 6-phosphate-dehydrogenase deficiency, or pre-existing Wilson's disease may be more susceptible to the effects of this material.

4. First Aid Measures

Inhalation:
Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
Ingestion:
Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. Call a physician.
Skin Contact:
In case of contact, wipe off excess material from skin then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Call a physician.
Eye Contact:
Immediately flush eyes with gentle but large stream of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Call a physician immediately.

5. Fire Fighting Measures

Fire:
Not considered to be a fire hazard. May form combustible fumes upon decomposition which may increase the flammability of a fire.
Explosion:
Reactions with incompatibles may pose an explosion hazard.
Fire Extinguishing Media:
Use any means suitable for extinguishing surrounding fire. Water spray may be used to keep fire exposed containers cool.
Special Information:
In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with

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full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

US Regulations (CERCLA) require reporting spills and releases to soil, water and air in excess of reportable quantities. The toll free number for the US Coast Guard National Response Center is (800) 424-8802. Ventilate area of leak or spill. Keep unnecessary and unprotected people away from area of spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Isolate from incompatible substances. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:
-OSHA Permissible Exposure Limit (PEL):
1 mg/m3 (TWA) for copper dusts & mists as Cu
-ACGIH Threshold Limit Value (TLV):
1 mg/m3 (TWA) for copper dusts & mists as Cu
Ventilation System:
A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.
Personal Respirators (NIOSH Approved):
If the exposure limit is exceeded and engineering controls are not feasible, a half facepiece particulate respirator (NIOSH type N95 or better filters) may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest.. A full-face piece particulate respirator (NIOSH type N100 filters) may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency, or respirator supplier, whichever is lowest. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.
Skin Protection:
Wear protective gloves and clean body-covering clothing.
Eye Protection:
Use chemical safety goggles and/or full face shield where dusting or splashing of solutions is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:
Dark green powder.
Odor:
Slight acetic acid odor.
Solubility:

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7.2 g/100 cc cold water; 20 g/100 cc hot water.
Density:
1.88
pH:
No information found.
% Volatiles by volume @ 21C (70F):
0
Boiling Point:
240C (464F) Decomposes.
Melting Point:
115C (239F)
Vapor Density (Air=1):
No information found.
Vapor Pressure (mm Hg):
No information found.
Evaporation Rate (BuAc=1):
No information found.

10. Stability and Reactivity

Stability:
Stable under ordinary conditions of use and storage.
Hazardous Decomposition Products:
May produce oxides of carbon and the contained metal.
Hazardous Polymerization:
Will not occur.
Incompatibilities:
Sodium hypobromite, acetylene, hydrazine, and nitromethane.
Conditions to Avoid:
Incompatibles.

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12. Ecological Information

Environmental Fate:
This material is expected to significantly bioaccumulate. This material has an experimentally-determined bioconcentration factor (BCF) of greater than 100. Bioaccumulation data for copper.
Environmental Toxicity:
This material is expected to be very toxic to aquatic life. The LC50/96-hour values for fish are less than 1 mg/l. The IC50/72-hour values for algae are less than 1 mg/l. Toxicity data for copper.

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13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

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16. Other Information

NFPA Ratings: Health: **2** Flammability: **0** Reactivity: **0**
Label Hazard Warning:
DANGER! CAUSES EYE BURNS. HARMFUL IF SWALLOWED. CAUSES IRRITATION TO SKIN AND RESPIRATORY TRACT.
Label Precautions:
Do not get in eyes.
Avoid breathing dust.
Keep container closed.
Use with adequate ventilation.
Wash thoroughly after handling.
Avoid contact with skin and clothing.
Label First Aid:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. In case of skin contact, wipe any excess material off skin and then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. In all cases, get medical attention.
Product Use:
Laboratory Reagent.
Revision Information:
No Changes.
Disclaimer:
****
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THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT BAKER, INC. WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

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Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)

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Ingestion	Wash out mouth with water. Drink plenty of water.
Advice for the doctor	Symptomatic treatment
Further information	See section 16 of MSDS

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents	Waterspray, foam, powder, carbon dioxide.
Restrictions	No restrictions.
Fire/explosion hazard	None
Main combustion gas	Carbon, nitrogen and sulfur oxides
Personal protection	Self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal protection	Gloves, respiratory protection.
Environmental precautions	No special precautions
Spillage procedure	Damp down. Avoid dust. Scoop into marked containers for disposal as chemical waste. Flush residues away with water.

7. HANDLING AND STORAGE

Handling

Occupational hygiene	Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Storage

Fire precautions	No special measures required
Storage facilities	Store in a cool, dry area with adequate ventilation
Segregation	Keep away from alkali.
Storage conditions	Keep containers closed. Sensitive to heat over 40 °C.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits	None. Ensure adequate ventilation

Exposure Controls

Occupational exposure controls	
General Personal Protection	Gloves, respiratory protection.
Hand protection	Chemical resistant protective gloves (EN 374). Recommended: permeation time >30 min. (level 2), material e.g. butyl or neopren. Observe glove manufacturers instructions.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Appearance	
Form	Powder
Colour	Blue

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Odour	None	

Important health safety and environmental information

pH	5 - 5.5	20 g/l
Boiling point	Not applicable	
Flash point	Not applicable	
Oxidising properties	None	
Solubility in water	80 g/l	at 30 °C
	80 g/l	90 °C

Other information

Melting point	> 250 °C	
Bulk density	657 kg/m3	
Thermal decomposition	230 °C	
Ignition temperature	480 °C	BAM

10. STABILITY AND REACTIVITY

Conditions to avoid	None.
Materials to avoid	None
Hazardous decomposition products	None under normal storage conditions

11. TOXICOLOGICAL INFORMATION

Acute toxicity			
- LD50 oral	> 2000 mg/kg	Rat	
Primary irritation			
(Skin)	Non-irritant	Rabbit	
(Eye)	Non-irritant	Rabbit	
Skin sensitisation	Sensitizing	Guinea Pig	OECD 406
Adverse effects in man	See 16 in MSDS		
Additional information			

12. ECOLOGICAL INFORMATION

Ecotoxicity

Bacterial toxicity			
	IC50	> 300 mg/l	3 hour
Fish toxicity	LC0	100 mg/l	48 hour Golden orfe
	LC50	> 100 mg/l	
Summary		Not toxic or harmful to aquatic organisms	

Persistance and degradability

Bioelimination	10-25%, DOC Analysis.	OECD 302B
Summary	Poorly eliminated by adsorption on effluent treatment sludge	
Behaviour in treatment plants	No inhibition. No nitrification inhibition known	

Additional Ecology Data

Phosphorus content	0 %	
Organohalogen content	0 %	
Metal content	2.04 %	Copper as organo-metal complex

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Tested material	Standardised product
Additional information	

13. DISPOSAL CONSIDERATIONS

Product disposal	Incineration, landfill. Observe local regulations.
Contaminated packaging	Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

KEEP AWAY FROM FOODSTUFFS

Not classified as dangerous goods

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Symbol and classification	Xi : Irritant
R-Phrases	R43 : May cause sensitisation by skin contact
S-Phrases	S22 : Do not breathe dust
	S24 : Avoid contact with skin
	S37 : Wear suitable gloves
Contains	C.I. Reactive Blue 21
EU Guideline	99/45

16. OTHER INFORMATION

Cases of respiratory sensitisation have been observed with reactive dyes.

Care should be taken to avoid inhalation.

Should an individual become sensitized a physician should be consulted and all contact with reactive dyes must cease immediately.

List of relevant R-phrases (Section 2)

R43 : May cause sensitisation by skin contact

Recommended restrictions on use

Huntsman textile, paper and leather dyes and chemicals are technical grade and unless otherwise stated or agreed are recommended only for industrial use in applications involving the pretreatment dyeing or finishing of textiles, paper or leather. Other intended uses including their use in consumer products governed by specific legislation or standards should be referred to the manufacturer. The data contained in the SDS apply only to Huntsman products sold under the stated trade names. Technical information in support will be provided by Huntsman at the request of competent authorities.

member of ETAD

MSDS Changes	15. REGULATORY INFORMATION
	S-Phrases

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least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.

Skin Contact:
Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: OPEN CUP: 79°C (174.2°F).

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO2).

Fire Hazards in Presence of Various Substances:
Flammable in presence of open flames and sparks, of heat.
Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available.
Slightly explosive in presence of open flames and sparks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water

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on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. est. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, metals, acids, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Powdered solid. Amorphous solid powder.)

Odor: Odorless.

Taste: Not available.

Molecular Weight: (44.05)n g/mole

Color: Off-white. White. Colorless.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point:
Softens at about 200°C (392°F) with decomposition.
Decomposition @ 228 deg. C.

Critical Temperature: Not available.

Specific Gravity: 1.19-1.31(Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) [redacted]

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility:
Soluble in cold water, hot water.
Insoluble in diethyl ether, acetone, petroleum solvents, aromatic hydrocarbons, esters.
Practically insoluble in animal and vegetable oils and chlorinated hydrocarbons.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Heat, ignition sources, flame, excess dust generation, incompatible materials.

Incompatibility with various substances: Reactive with oxidizing agents, metals, acids, alkalis.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Incompatible with oxidizing agents (perchlorates, nitrates, etc.), reactive metals (sodium, calcium, zinc. etc.), sodium or calcium hypochlorite, materials reactive with hydroxyl compounds. Reaction with peroxides may result in violent decomposition of peroxide possibly creating and explosion.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals:
Acute oral toxicity (LD50): 14700 mg/kg [Mouse].
Acute oral toxicity (LD50): > 20000 mg/kg [Rat].

Chronic Effects on Humans: CARCINOGENIC EFFECTS: 3 (Not classifiable for human.) by IARC.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: May cause cancer (tumorigenic) based on animal studies. No human data found at this time.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects:
Skin: May cause skin irritation.
Eyes: May cause eye irritation.
Ingestion: May cause gastrointestinal (digestive) tract irritation. May affect behavior/central nervous system (symptoms may include general depressed activity, altered sleep time, muscle weakness). May also affect blood and metabolism.
Inhalation: May cause respiratory tract irritation.
Chronic Potential Health Effects:
Inhalation or ingestion for prolonged period of time may affect blood and metabolism, and behavior.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4)

May cause cancer (tumorigenic) based on animal studies. No human data found at this time.

Section 12: Ecological Information

(b)(4)

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

(b)(4)

(b)(4)

[redacted]

Flammability: 2

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves.
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent.
Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/10/2005 08:47 PM

Last Updated: 11/06/2008 12:00 PM

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall ScienceLab.com be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if ScienceLab.com has been advised of the possibility of such damages.

(b)(4)

[redacted]

(b)(4)

(b)(4)

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

corresponding RQs	
SARA Section 302 Extremely Hazardous Substances	None of the chemicals in this product have a TPQ.
Section 313	No chemicals are reportable under Section 313.
Clean Air Act:	This material does not contain any hazardous air pollutants. This material does not contain any Class 1 Ozone depletors. This material does not contain any Class 2 Ozone depletors.
Clean Water Act:	None of the chemicals in this product are listed as Hazardous Substances under the CWA. None of the chemicals in this product are listed as Priority Pollutants under the CWA. None of the chemicals in this product are listed as Toxic Pollutants under the CWA.

(b)(4) [redacted]

European Labeling in Accordance with EC Directives

Hazard Symbols:Not available

Risk Phrases:

Safety Phrases:

S 24/25 Avoid contact with skin and eyes.

(b)(4) [redacted]

(b)(4) [redacted]

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantibility or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential, or exemplary damages howsoever arising, even if the company has been advised of the possibility of such damages.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent

K101128 | A4

March 02, 2011

FDA CDRH DMC

MAR - 4 2011

Received K24

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information - 510(k) Premarket Notification – K101128

This letter constitutes Filligent (HK) Limited's response to CDRH's request for additional information, which was received by email on February 22 and February 25, 2011. It forms part of our total submissions to date – namely:

- 510(k) Premarket Notification, dated April 20, 2010
- Additional Information, dated June 4, 2010 submitted in response to CDRH's request for additional information, which was dated and received by email on April 28, 2010
- Additional Information, dated November 13, 2010 submitted in response to CDRH's request for additional information, which was dated May 21, 2010
- Additional Information, dated February 19, 2011, submitted in response to CDRH's request additional information, which was dated December 29, 2010

Each request is listed in the following pages, together with our response.

We believe that this response will provide adequate information to reach a determination of substantial equivalence. Nevertheless, if you require additional information, please do not hesitate to contact us at:

Filligent (HK) Limited

7th Floor, 69 Jervois Street

Sheung Wan, Hong Kong

Telephone: +852 2542 2400

Facsimile: +852 2542 2411

Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent
creating
global health choices

March 02, 2011

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information - 510(k) Premarket Notification – K101128

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Each request is listed in the following pages, together with our response.

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Filligent (HK) Limited

7th Floor, 69 Jervois Street

Sheung Wan, Hong Kong

Telephone: +852 2542 2400

Facsimile: +852 2542 2411

Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

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- Questions 1

2.0 Labeling

- Questions 2 to 4

3.0 Shelf-Life

- Questions 1 to 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

1 Indications for Use

CDRH Questions

1. Please add the following statement to the Indications for Use statement "Correlation between in vitro testing results and any clinical event has not been tested" to the free-standing Indications-for-Use statement and Indications-for-Use section of the 510(k) Summary. This should be placed just after the list of tested influenza strains.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

1. Please add the following statement to the Indications for Use statement "Correlation between in vitro testing results and any clinical event has not been tested" to the free-standing Indications-for-Use statement and Indications-for-Use section of the 510(k) Summary. This should be placed just after the list of tested influenza strains.

The wording “Correlation between in-vitro testing results and any clinical event has not been tested” has been added to the Indications for Use/Statement of Intended Use and Indications for Use/Statement of Intended Use section of the 510(k) Summary.

The amended Indications-for-Use statement and 510(k) summary is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

4 Indications for Use Statement

510(k) Number:

K101128.

Device Name:

BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A

Indications for Use:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007,A/Wisconsin/67/2005,), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

Prescription Use _____	AND/OR	Over-The Counter Use ___X___
(21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded and expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of microorganisms, body fluids and particulate material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5 510(k) Summary

5.1 Applicant and Correspondent

Name: Filligent (HK) Limited

Address: 7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

Contact Person: Melissa Mowbray-d'Arbela
Chief Executive Officer

Phone: (852) 2542 2400

Date of Preparation: March 2, 2011

5.2 Manufacturer

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

5.3 Name of Device

Trade/Proprietary/Model Name: BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A
Premium BF-200-3013A

Common Name: Surgical Facemask

Classification Name: Mask, Surgical

Classification Regulation: 878.4040

Panel: General Hospital

Product Code: FXX

Recognized Performance Std: ASTM F2100-07 (refer to submission)

5.4 Devices to Which New Device is Substantially Equivalent

Device Name: Prestige Ameritech Face Mask
Manufacturer: Prestige Ameritech
Reference: K061716

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.5 Device Description

The BioFriend™ BioMask™ surgical facemask is offered in two mask styles, Model: BF-200-2001A ("Universal") and Model: BF-200-3013A ("Premium"). The Universal model is a standard flat mask with pleats, while the Premium model is flat-folded and expands into a convex-shaped mask. The Premium model also has ear adjusters and an anti-fog nose flap. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in these devices are typical construction materials commonly used in surgical facemasks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second inner layer is treated with copper and zinc. Both layers inactivate influenza viruses using different mechanisms of action. Masks are held in place on the wearer with elastic loops and contain a malleable metal nosepiece strip.

5.6 Statement of Intended Use

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

There are two models: (1) Universal (BF-200-2001A) - is a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.7 Summary of Technological Characteristics

The BioFriend™ BioMask™ surgical facemasks have substantially equivalent filter and barrier properties as the predicate device, and conform to the recognized FDA consensus standard ASTM F2100-07 Standard Specification for Performance of Materials used in Medical Face Masks. Both models of the BioFriend™ BioMask™ surgical facemask are constructed from the same materials and layers, and are identical in all respects other than shape. The outer layer of both models is coated with a hydrophilic plastic that allows aerosolized droplets contacting the surface of the mask to be rapidly absorbed into the inner layers. Both the outer and second inner layers are treated with different compounds that independently inactivate viruses through different mechanisms of action. Laboratory *(in vitro)* test results demonstrate that the BioFriend™ BioMask™ surgical facemasks kill ("inactivate") 99.99% (≥4-logs) of 15 different strains of Influenza A and B viruses, including the circulating 2009 pandemic H1N1, recent vaccine isolates, major reassortments and avian, swine and equine isolates after 5 minutes contact with the mask surface.

The BioFriend™ BioMask™ surgical facemasks have been tested for, and appropriately passed standardized tests for, fluid penetration resistance, particulate filtration efficiency, bacterial filtration efficiency, flammability, and breathing resistance. The device as a whole has been shown to be biocompatible through standardized tests for irritation, sensitization and extractables.

The materials of construction used in the BioFriend™ BioMask™ surgical facemasks are equivalent to those of the predicate device. The devices as a whole are substantially equivalent to the predicate device.

5.8 Brief description of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

- Bacterial Filtration Efficiency – ASTM F2101
- Sub-micron Particulate Filtration Efficiency – ASTM F2299
- Fluid Penetration Resistance – ASTM F1862
- Breathing Resistance – MIL-M-3654C
- Flammability Testing – 16 CFR 1610
- Biocompatibility, Irritation – ISO 10993-10
- Biocompatibility, Sensitization – ISO 10993-10
- Biocompatibility, Chemical Characterization – ISO 10993-18

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.9 Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Not applicable.

5.10 Conclusions drawn from the nonclinical and clinical tests

Standardized testing has shown that the construction materials used in both models of the BioFriend™ BioMask™ surgical facemask are substantially equivalent to those of the predicate device. The devices as a whole have been demonstrated to be biocompatible through irritation and sensitization testing, with toxicological assessment of the devices' components which could potentially be released with inhalation or salivary contact, indicating the devices are safe for use in the intended application. Laboratory testing has demonstrated the devices' efficacy. Both models of the BioFriend™ BioMask™ surgical facemask have been shown to be substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

2 Labeling

CDRH Questions

2. The following objectionable and misleading phrases remain in the BioMask labeling:

"kills **99.99%** of FLU VIRUSES tested*"

"**tested seasonal & pandemic** flu strains*"

"inactivates **99.99%** of **H1N1** influenza virus tested*

"**Kills (inactivates) 99.99%** of the following tested **influenza viruses** on 5 minutes contact..."

"**99.99% of influenza viruses**"

The effect of the bolding and font size used is to imply "**kills 99.99% of flu viruses**" and "**inactivates 99.99% of H1N1**" influenza viruses. Such claims are incorrect. This use of bolding and font size changes may be misinterpreted and these statements should be revised. You may either "bold" or increase the font size for "tested" in all of these phrases to make them equivalent to the rest of the text.

Where you have "bolded" the phrase "99.99% of influenza viruses" in the middle of a long paragraph, please remove the "bold" font or replace it with "99.99% of tested strains of influenza viruses".

3. On some box panels, you use the term "high barrier protection" without the ASTM F2100-07 Standard reference.

Please remove the isolated phrase "high barrier protection" or revise it wherever it is used to remove "protection" and include "meeting ASTM F2100-07 Standard".

4. The FDA guidance document on Surgical Masks does not discuss or advise claims based on a perception of "cool" for a Delta-P value of 2 to 3, much less an extrapolation to a claim for "easy breathing". This claim is vague and open to misinterpretation. As previously requested, this claim should be deleted.

Please delete this claim.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

2. The following objectionable and misleading phrases remain in the BioMask labeling:

"kills 99.99% of FLU VIRUSES tested*"

"tested seasonal & pandemic flu strains*"

"inactivates 99.99% of H1N1 influenza virus tested*

"Kills (inactivates) 99.99% of the following tested influenza viruses on 5 minutes contact..."

"99.99% of influenza viruses"

The effect of the bolding and font size used is to imply "kills 99.99% of flu viruses" and "inactivates 99.99% of H1N1" influenza viruses. Such claims are incorrect. This use of bolding and font size changes may be misinterpreted and these statements should be revised. You may either "bold" or increase the font size for "tested" in all of these phrases to make them equivalent to the rest of the text.

Where you have "bolded" the phrase "99.99% of influenza viruses" in the middle of a long paragraph, please remove the "bold" font or replace it with "99.99% of tested strains of influenza viruses".

The phrases:

"kills 99.99% of FLU VIRUSES tested*"

"tested seasonal & pandemic flu strains*"

"inactivates 99.99% of H1N1 influenza virus tested*

"Kills (inactivates) 99.99% of the following tested influenza viruses on 5 minutes contact..."

"99.99% of influenza viruses"

Have been revised in accordance with the FDA's request.

The bolded phrase "99.99% of influenza viruses" in the Indications for Use Statement on the labeling has been replaced with the phrase "99.99% of tested strains of influenza viruses".

The amended labeling is provided at the end of this section.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

3. On some box panels, you use the term "high barrier protection" without the ASTM F2100-07 Standard reference.

Please remove the isolated phrase "high barrier protection" or revise it wherever it is used to remove "protection" and include "meeting ASTM F2100-07 Standard".

The isolated phrase “high barrier protection” has been removed from the labeling.

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

4. The FDA guidance document on Surgical Masks does not discuss or advise claims based on a perception of "cool" for a Delta-P value of 2 to 3, much less an extrapolation to a claim for "easy breathing". This claim is vague and open to misinterpretation. As previously requested, this claim should be deleted.

Please delete this claim.

The claim “easy breathing” has been removed from the labeling.

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Revised Labeling

The revised labeling for the BioFriend™ BioMask™ surgical facemask is provided in the following pages.

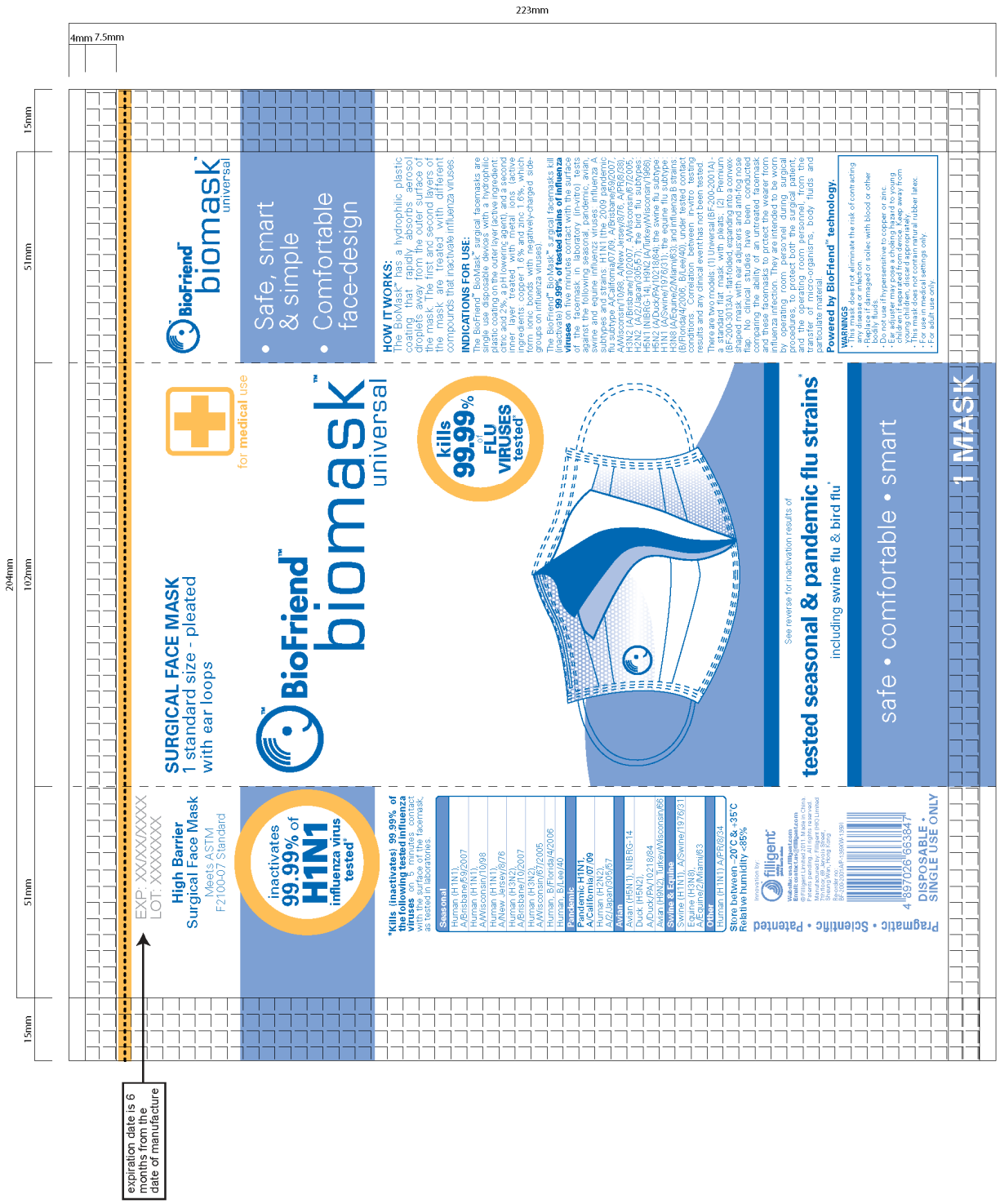
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

K101128

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Bag – Principle Display Panel - Front & Reverse



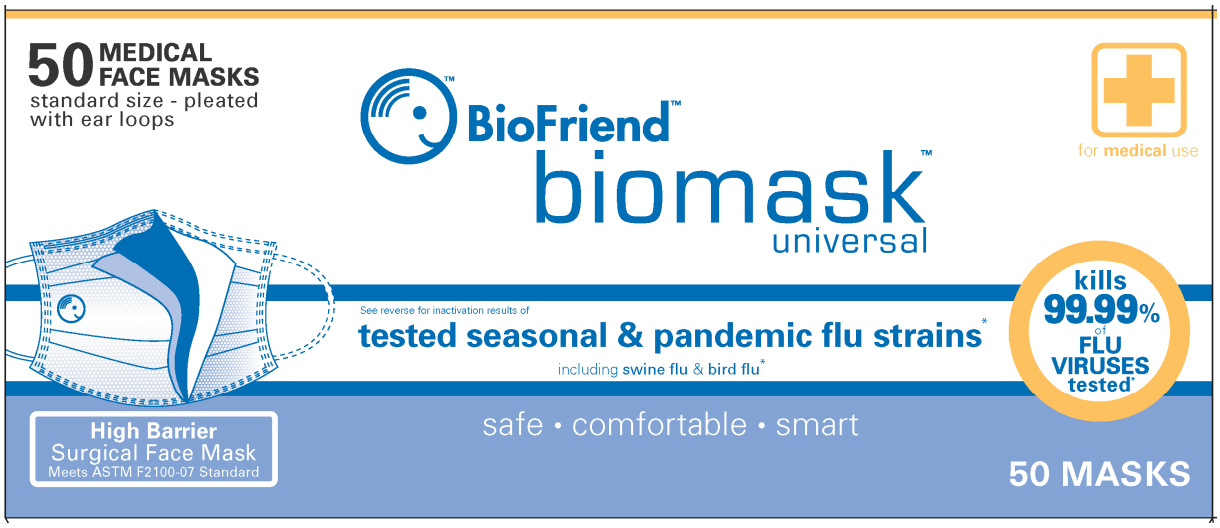
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Complete Box

Box - Principal Display Panel – Front & Reverse



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

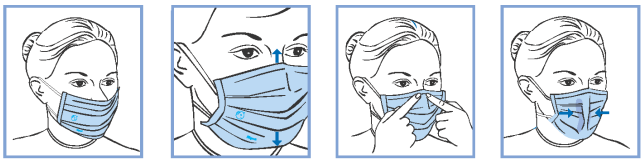
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box - Side Panel 1

BioFriend™
biomask™
universal

FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask.



1 Put loops around ears.

2 Adjust mask over nose & under chin.

3 Press forefingers down on both sides of nose.

4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

DISPOSABLE • SINGLE USE ONLY

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are killed (inactivated).

* **Kills (inactivates) 99.99% of the following tested influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal	Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Victoria/3/75 Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40
Pandemic	Pandemic H1N1, A/California/07/09 Human (H3N2), A/Hong Kong/8/68 Human (H2N2), A/2/Japan/305/57
Avian	Avian (H5N1), NIBRG-14 Duck (H5N2), A/Duck/PA/10218/84 Avian (H9N2), Turkey/Wisconsin/66
Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

Powered by BioFriend™ technology.

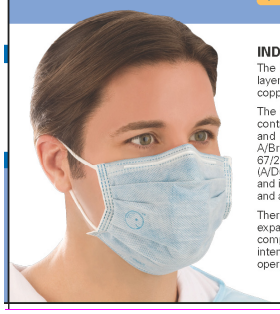
Box – Side Panel 2

BioFriend™
biomask™
universal

DISPOSABLE
SINGLE USE ONLY

inactivates **99.99%** of **H1N1** influenza virus tested*

- Safe, smart & simple
- Comfortable face-design



INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) **99.99% of tested strains of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, H2N2 (A/2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in-vitro testing results and any clinical event has not been tested.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

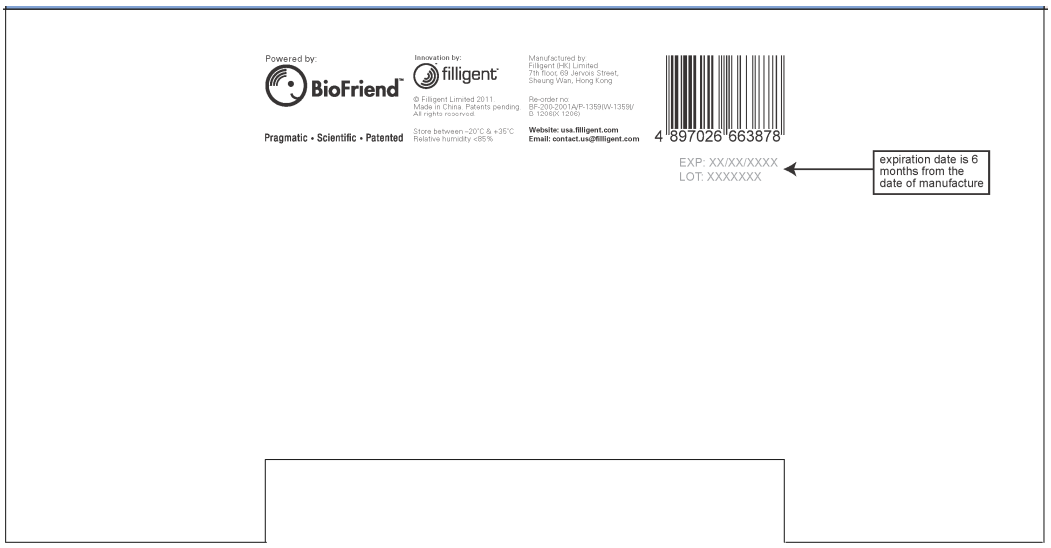
WARNINGS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- Do not use if hypersensitive to copper or zinc.
- Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately.
- This mask does not contain natural rubber latex.
- For use in medical settings only.
- For adult use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box – Lid

Box – Bottom

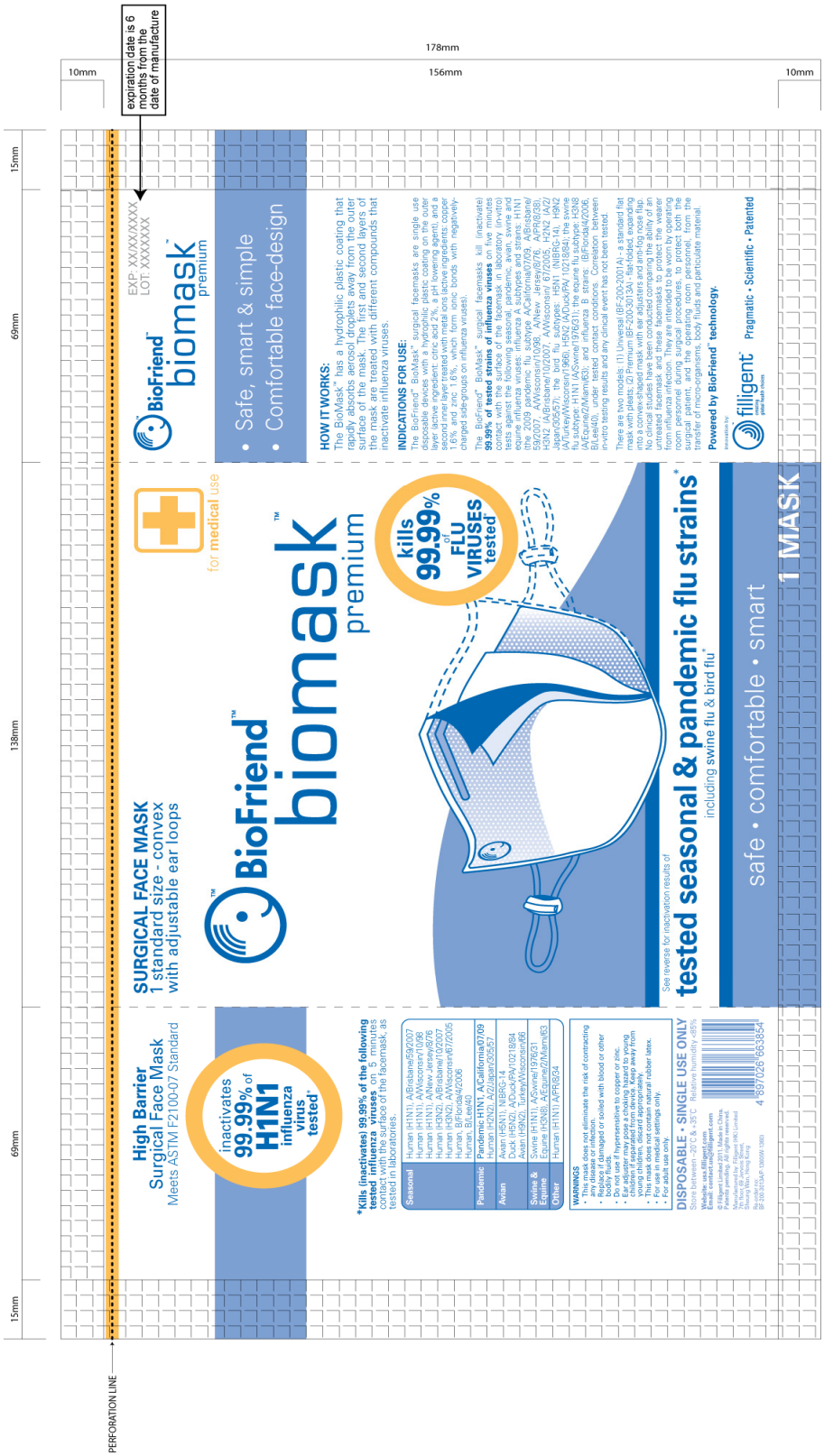


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-3013A

Bag - Principal Display Panel – Front & Reverse

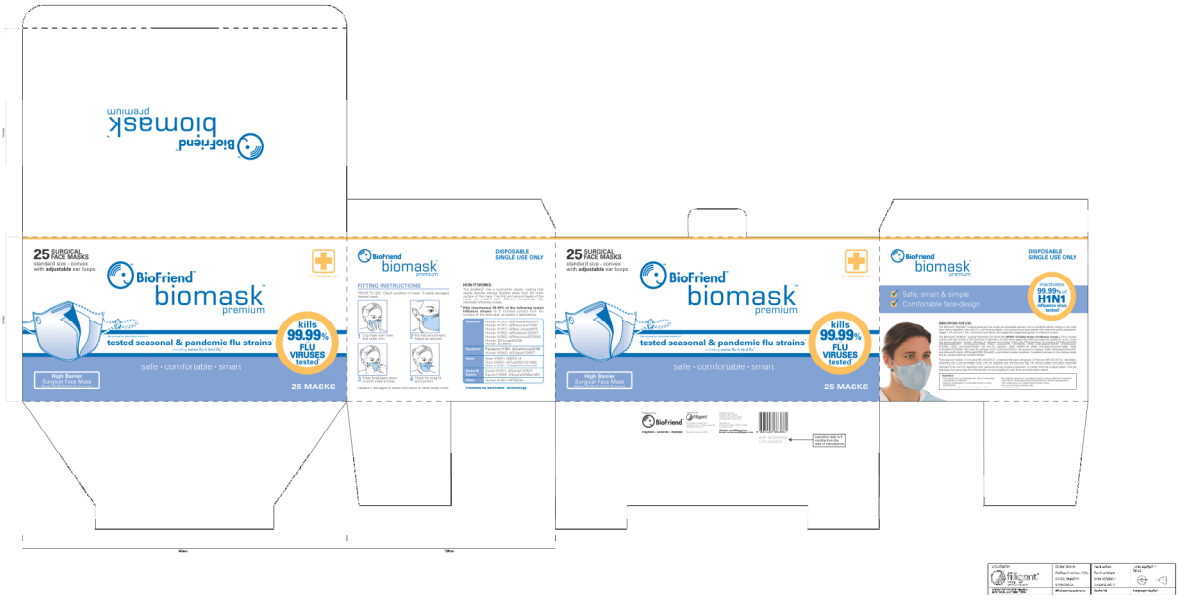


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-3013A

Complete Box



Box - Principal Display Panel – Front & Reverse

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box - Side Panel 1

BioFriend™
biomask™
premium

DISPOSABLE SINGLE USE ONLY

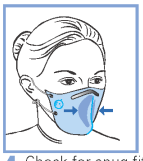
FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask.

1 Cup mask over nose and under chin.

2 Put loop around ears. Adjust as required.

3 Press forefingers down on both sides of nose.



4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

HOW IT WORKS:

The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the outer surface of the mask. The first and second layers of the mask are treated with different compounds that inactivate influenza viruses.

* **Kills (inactivates) 99.99% of the following tested influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal	Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human, B/Florida/4/2006 Human, B/Lee/40
Pandemic	Pandemic H1N1, A/California/07/09 Human (H2N2), A/2/Japan/305/57
Avian	Avian (H5N1), NIBRG-14 Duck (H5N2), A/Duck/PA/10218/84 Avian (H9N2), Turkey/Wisconsin/66
Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

Powered by BioFriend™ technology.

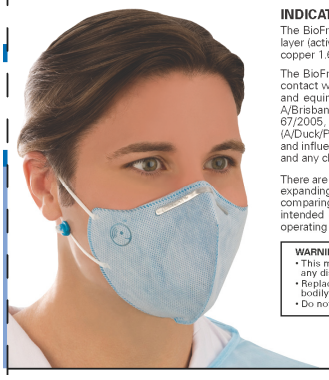
Box – Side Panel 2

BioFriend™
biomask™
premium

DISPOSABLE SINGLE USE ONLY

- Safe, smart & simple
- Comfortable face-design

inactivates **99.99%** of **H1N1** influenza virus tested*



INDICATIONS FOR USE:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) **99.99% of tested strains of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, H2N2 (A/2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in-vitro testing results and any clinical event has not been tested.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

WARNINGS

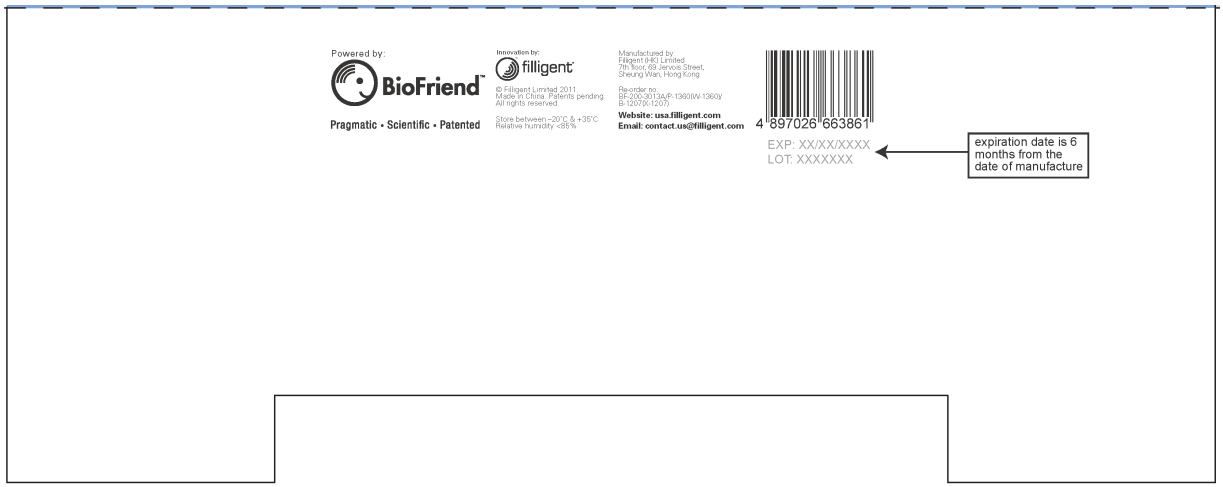
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- Do not use if hypersensitive to copper or zinc.
- Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately.
- This mask does not contain natural rubber latex.
- For use in medical settings only.
- For adult use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box – Lid

Box – Bottom



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

3 Shelf-Life

CDRH Questions

1. In May of 2010, FDA asked that you provide a report determining the actual levels of the antiviral agents through the shelf life of your device (FDA Question 24, May, 2010. In November, 2010, you responded that you planned to perform that testing at the 12 month real time shelf life testing. However, this planned testing does not appear in the shelf life testing protocol which you have submitted to FDA in response to our December, 2010 Question 22. Please provide a corrected complete shelf life testing protocol which includes all of the stability and performance testing planned for the ongoing, real time evaluation of the BioMask, including the evaluation of the pH of the outer mask layer and the quantitative analyses of citric acid, copper and zinc and the test schedule intervals for these.

2. Please add the current expiration date for your devices to all of the device labeling. Since only the 6 month real time test data is currently available, that is what should appear of the device labeling now.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

1. In May of 2010, FDA asked that you provide a report determining the actual levels of the antiviral agents through the shelf life of your device (FDA Question 24, May, 2010. In November, 2010, you responded that you planned to perform that testing at the 12 month real time shelf life testing. However, this planned testing does not appear in the shelf life testing protocol which you have submitted to FDA in response to our December, 2010 Question 22. Please provide a corrected complete shelf life testing protocol which includes all of the stability and performance testing planned for the ongoing, real time evaluation of the BioMask, including the evaluation of the pH of the outer mask layer and the quantitative analyses of citric acid, copper and zinc and the test schedule intervals for these.

The corrected testing procedure for assessing the shelf-life of the BioFriend™ BioMask™ surgical facemask - Shelf-Life Assessment Procedure for BioFriend™ BioMask™ Surgical Facemask Models: Universal: BF-200-2001A & Premium: BF-200-3013A. Revision E Date: March 01, 2011 – is appended to the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

2. Please add the current expiration date for your devices to all of the device labeling. Since only the 6 month real time test data is currently available, that is what should appear on the device labeling now.

The device will be labeled with an expiration date that is 6 months from the date of manufacture.

The amended labeling is provided at the end of section 2.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Appendix

Contents

Shelf-Life Assessment Procedure for BioFriend™ BioMask™ Surgical Facemask Models: Models: Universal: BF-200-2001A & Premium: BF-200-3013A. Revision E, Date: March 01, 2011 3A-2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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STRICTLY CONFIDENTIAL
NOT FOR DISTRIBUTION

Shelf-Life Assessment Procedure

For

BioFriend™ BioMask™ Surgical Facemasks

(b)(4) Shelf-Life Assessment Procedure

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Shelf-Life Assessment Procedure

(b)(4) Shelf-Life Assessment Procedure

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filligent
creating
global health choices

K101128/A001

May 4, 2010

FDA CDRH DMC 438
MAY - 6 2010
Received

Document Mail Center – WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr Murphey

Re: Supplement to 510(k) Premarket Notification – K101128

Our firm has submitted a 510(k) premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128). On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Infection Control Devices Branch, was received requesting Filligent to provide further information.

The enclosed submission is a response to such request and constitutes a supplement to the 510(k) Premarket Notification – K101128.

Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Supplementary Response to FDA Request

Our firm has submitted a premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128, the "510(k) Submission"). On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Infection Control Devices Branch, was received requesting Filligent to provide further information:

As we review your 510(k) submission, it is very important that we have a complete description of the antimicrobial agents in the Filligent BioMasks and how they interact with each other and their safety for wearers of the devices. Please provide the following information, either with respect to its current location in the file or as additional information (we have looked for these items and could not find them):

1. The MEC (minimum effective concentration) of the antimicrobial agents in your device - citric acid, copper, zinc. If you believe that (b)(4) [redacted] *to the antimicrobial activity, please include them as well.*

2. The acceptance criteria for the pH of the outer layer of your devices

3. The pH of the second layer of your devices when the aerosols contacting the outer layer are "drawn into" the second layer

4. The acceptance criteria for the levels of citric acid, copper and zinc in your devices

5. The MSDS sheets for citric acid, (b)(4) [redacted]

6. Please provide the levels of citric acid, copper and zinc in your devices by ugm or mgm per unit of area such as cm2 for your devices

7. Please provide the total amounts of citric acid, copper and zinc per total, complete device for each of your mask models

8. Please provide the dimensions and area for each of your two mask models

9. Please identify the contribution of the (b)(4) [redacted] *antimicrobial activity of your device*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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10. Please state whether or not any "anti-fog" compound has been added to the polyurethane nose sponge on the Premium BF 200-3013 mask or where it is the presence of untreated polyurethane which is considered to provide the anti-fog function

If the above information is not already in the file, please provide it to Mr. Elliott and to me electronically as soon as you can. Please also send a copy of this material to the Document mail Center so that it can be officially added to the contents of your file.

We may have additional questions later as we proceed with this review. If that is the case, we will send them to you. We expect to request consultation from the Center for Drug Evaluation and Research (CDER) on this interesting submission. However, we must be sure before we place the request that all of the information which CDER will need will be available in the file. If you have any questions about the information needed, please let me know.

Thank you very much for your assistance in providing this information.

Regards,
Sheila A. Murphey, MD

. . . . . .

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

1. The MEC (minimum effective concentration) of the antimicrobial agents in your device - citric acid, copper, zinc. If you believe that Tween 20 and/or polyvinyl alcohol contribute to the antimicrobial activity, please include them as well.

Questions 1 to 3 will be addressed in a subsequent written response to the FDA on or about May 21, 2010. Additional MEC GLP testing has been initiated by Filligent with Microbiotest Inc. Salt Lake City, Utah to supplement internal test data characterizing the antimicrobial agents in the BioMask. Preliminary test data is expected May 12, 2010 with audited GLP reports on May 21, 2010. A complete response on these issues will be made to the FDA at that time.

2. The acceptance criteria for the pH of the outer layer of your devices

See response to Question 1.

3. The pH of the second layer of your devices when the aerosols contacting the outer layer are "drawn into" the second layer

See response to Question 1.

4. The acceptance criteria for the levels of citric acid, copper and zinc in your devices

In manufacturing, a percentage weight gain of (b) (b) processing has been set as the acceptance criteria for the outer layer polypropylene coated with the hydrophilic plastic. The textile is rejected when the percentage weight gain of the polypropylene textile after processing (b)(4) (b)(4) The amount of citric acid contained within the plastic coating can be calculated from the composition of the formulation (b)(4) Polypropylene with a percentage (b)(4) (b)(4)

The acceptance criterion for the levels of copper and zinc ions in the cellulose/polyester layer (b)(4) (b)(4) The final cellulose/polyester textile layer is rejected when the copper or zinc ions are below (b)(4) Copper and zinc ions within the cellulose/polyester textile are measured (b)(4)

5. The MSDS sheets for (b)(4)

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The MSDS sheets for citric acid, copper acetate, zinc acetate and CI Reactive Blue 21 are provided in Appendix 1:

(b)(4)

[redacted]

The MSDS sheets for the remaining chemical constituents of the BioFriend™ BioMask™ are provided in Appendix 2:

(b)(4)

[redacted]

6. Please provide the levels of citric acid, copper and zinc in your devices by ugm or mgm per unit of area such as cm^2 for your devices

See response to Question 7.

7. Please provide the total amounts of citric acid, copper and zinc per total, complete device for each of your mask models

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical face masks and are being

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second layer is treated with copper and zinc. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip. One model is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard "comfort" features such ear adjusters and an anti-fog nose insert. The materials used in the construction of the Universal BF-200-2001 and Premium BF-200-3013 are of approximately the same total surface area (b)(4) respectively (Table 2). The composition of the antimicrobial agents contained in the BioFriend™ BioMask™ surgical facemasks, is summarized in Table 1, and is based on an average surface area of (b)(4) (also refer to Tables 15-4 and 15-5, page 15-4 of the 510(k) Submission). The minimum and maximum levels of the antimicrobial agents in the devices, as defined by the acceptance criteria, are also given.

(b)(4)

[1] Based on average total surface area of (b)(4)
[2] min and max as calculated from the acceptance criteria

8. Please provide the dimensions and area for each of your two mask models

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. One is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard "comfort" features such

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

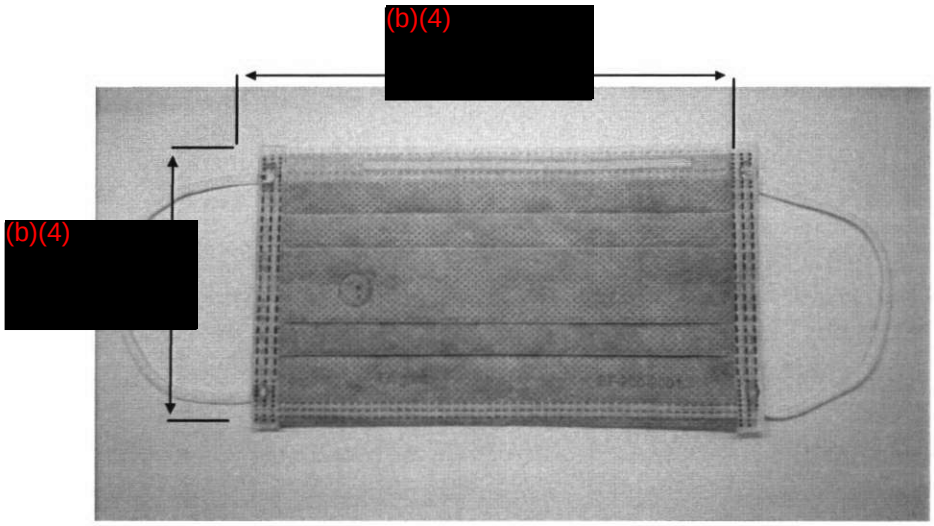
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

ear adjusters and an anti-fog nose insert. The major dimensions for each device are summarized in Table 2, and Figures 1 and 2. Both the Universal BF-200-2001 and Premium BF-200-3013 contain approximately the same total surface area of material of ~288 cm^2 (also refer to Table 15-5, page 15-4 of 510(k) submission).

(b)(4)

[redacted]

Figure 1 Major Dimensions of the BioFriend™ BioMask™ Universal BF-200-2001



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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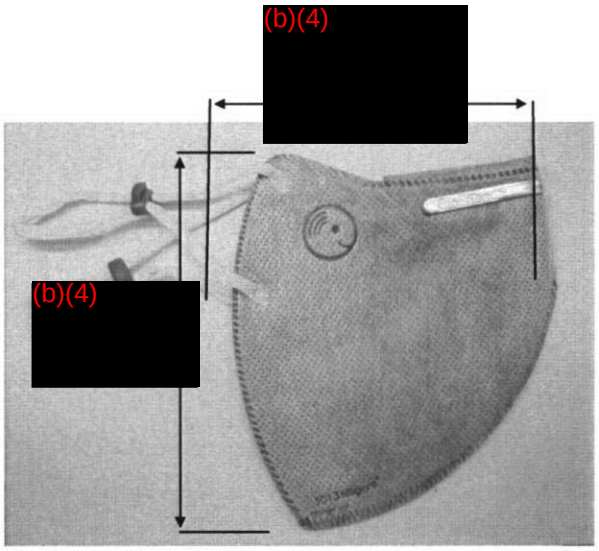
Figure 2 Major Dimensions of the BioFriend™ BioMask™ Premium BF-200-3013



9. Please identify the contribution (b)(4) the antimicrobialactivity of your device

(b)(4)

10. Please state whether or not any "anti-fog" compound has been added to the polyurethane nose sponge on the Premium BF 200-3013 mask or where it is the presence of untreated polyurethane which is considered to provide the anti-fog function

No "anti-fog" compounds have been added to the polyurethane sponge. The presence of untreated polyurethane on the inside of the nose-flap is used to improve seal of the nose-flap around the nose to help prevent glasses and face shields from fogging.

[1] Lawton, E. A. (1958) The thermal stability of copper phthalocyanine. *J. Phys. Chem.*62 (3): 384

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Appendix 1

Contents

(b)(4)

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Appendix 2

Contents

(b)(4)

[redacted]

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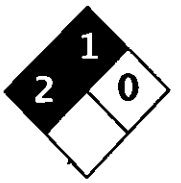
Appendix 1-A: Citric Acid MSDS



Health	2
Fire	1
Reactivity	0
Personal Protection	E

Material Safety Data Sheet
Citric acid MSDS

Section 1: Chemical Product and Company Identification

Product Name: Citric acid

Catalog Codes: SLC5449, SLC2665, SLC4453, SLC1660, SLC3451

CAS#: 77-92-9

RTECS: GE7350000

TSCA: TSCA 8(b) inventory: Citric acid

CI#: Not available.

Synonym: 2-Hydroxy-1,2,3-propanetricarboxylic acid

Chemical Name: Citric Acid

Chemical Formula: C6H8O7

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Citric acid	77-92-9	100

Toxicological Data on Ingredients: Citric acid: ORAL (LD50): Acute: 5040 mg/kg [Mouse]. 3000 mg/kg [Rat].

Section 3: Hazards Identification

Potential Acute Health Effects:
Hazardous in case of eye contact (irritant), of inhalation (lung irritant). Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion. The amount of tissue damage depends on length of contact. Eye contact can result in corneal damage or blindness. Skin contact can produce inflammation and blistering. Severe over-exposure can produce lung damage, choking, unconsciousness or death.

Potential Chronic Health Effects:
Slightly hazardous in case of skin contact (sensitizer).
CARCINOGENIC EFFECTS: Not available.
MUTAGENIC EFFECTS: Not available.
TERATOGENIC EFFECTS: Not available.
DEVELOPMENTAL TOXICITY: Not available.
The substance may be toxic to teeth.
Repeated or prolonged exposure to the substance can produce target organs damage. Repeated exposure of the

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Appendix 1-A: Citric Acid MSDS

eyes to a low level of dust can produce eye irritation. Repeated skin exposure can produce local skin destruction, or dermatitis. Repeated inhalation of dust can produce varying degree of respiratory irritation or lung damage.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Skin Contact:
In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact:
Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: 1010°C (1850°F)

Flash Points: Not available.

Flammable Limits: LOWER: 0.28 Kg/M3 (Dust) UPPER: 2.29 Kg/M3 (Dust)

Products of Combustion: These products are carbon oxides (CO, CO2).

Fire Hazards In Presence of Various Substances:
Slightly flammable to flammable in presence of heat.
Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Slightly explosive in presence of open flames and sparks.
Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

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Appendix 1-A: Citric Acid MSDS

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Eliminate all ignition sources. Call for assistance on disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, reducing agents, metals, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:
Safety glasses. Lab coat. Gloves (impervious). Dust respirator. Be sure to use an approved/certified respirator or equivalent. The dust respirator should be used for conditions where exposure has exceeded recommended exposure limits, dust is apparent, and engineering controls(adequate ventilation) are not feasible.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:
No exposure guidelines have been established.
ACGIH, NIOSH and OSHA have not developed exposure limits for this product.
The exposure limits given below are for particulates not otherwise classified:
ACGIH: 10 mg/m3 TWA (Total Inhalable fraction); 3 mg/m3 TWA (Respirable fraction)
OSHA: 15 mg/m3 TWA (Total dust); 5 mg/m3 TWA (Respirable Fraction)

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Crystalline powde)

Odor: Odorless.

Taste: Acid. (Strong.)

Molecular Weight: 192.13 g/mole

Color: Not available.

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Appendix 1-A: Citric Acid

pH (1% soln/water): Not available.

Boiling Point: Decomposes.

Melting Point: 153°C (307.4°F)

Critical Temperature: Not available.

Specific Gravity: 1.665 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: The product is more soluble in water; log(oil/water) = -1.7

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water, diethyl ether.

Solubility:
Soluble in cold water, hot water, diethyl ether.
Insoluble in benzene.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents, reducing agents, metals, alkalis.

Corrosivity:
Corrosive in presence of aluminum, of zinc, of copper.
Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Incompatible with oxidizing agents, potassium tartrate, alkali, alkaline earth carbonates and bicarbonates, acetates, and sulfides, metal nitrates

Special Remarks on Corrosivity: Will corrode copper, zinc, aluminum and their alloys.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation, Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 3000 mg/kg [Rat].

Chronic Effects on Humans: May cause damage to the following organs: teeth.

Other Toxic Effects on Humans:

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Appendix 1-A: Citric Acid

Hazardous in case of inhalation (lung irritant).
Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion.

Special Remarks on Toxicity to Animals: LDL[Rabbit] - Route: oral; Dose: 7000mg/kg

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects:
Skin: Causes mild to moderate skin irritation. May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material.
Eyes: Causes moderate to severe eye irritation and possible injury.
Ingestion: May cause gastrointestinal (digestive) tract irritation with nausea, vomiting, diarrhea. Excessive intake may cause erosion of teeth and hypocalcemia (calcium deficiency in blood). May affect behavior/central nervous system (tremor, convulsions, muscle contraction or spasticity).
Inhalation: Causes moderate respiratory tract and mucous membrane irritation.
Chronic Potential Health Effects:
Frequent intake of citrated beverages may cause erosion of dental enamel and irritation of mucous membranes.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Citric acid

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): CLASS E: Corrosive solid.

DSCL (EEC):

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Appendix 1-A: Citric Acid

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R36/37/38- Irritating to eyes, respiratory system and skin.
S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S37/39- Wear suitable gloves and eye/face protection.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: e

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves (impervious).
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.
Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 04:56 PM

Last Updated: 11/06/2008 12:00 PM

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(b)(4) [redacted]

Potential Health Effects

Inhalation:
Causes irritation to respiratory tract, symptoms may include coughing, sore throat, and shortness of breath. May result in ulceration and perforation of respiratory tract. When heated, this compound may give off copper fume, which can cause symptoms similar to the common cold, including chills and stuffiness of the head.
Ingestion:
May cause burning pain in the mouth, esophagus, and stomach. Hemorrhagic gastritis, nausea, vomiting, abdominal pain, metallic taste, and diarrhea may occur. If vomiting does not occur immediately systemic copper poisoning may occur. Symptoms may include capillary damage, headache, cold sweat, weak pulse, kidney and liver damage, central nervous excitation followed by depression, jaundice, convulsions, blood effects, paralysis and coma. Death may occur from shock or renal failure.
Skin Contact:
May cause irritation with redness and pain.
Eye Contact:
Corrosive. May cause irritation, redness, pain, blurred vision, discoloration, and damage.
Chronic Exposure:
Prolonged or repeated skin exposure may cause dermatitis. Prolonged or repeated exposure to dusts of copper salts may cause discoloration of the skin or hair, blood and liver damage, ulceration and perforation of the nasal septum, runny nose, metallic taste, and atrophic changes and irritation of the mucous membranes.
Aggravation of Pre-existing Conditions:
Persons with pre-existing skin disorders, impaired liver, kidney, or pulmonary function, glucose 6-phosphate-dehydrogenase deficiency, or pre-existing Wilson's disease may be more susceptible to the effects of this material.

4. First Aid Measures

Inhalation:
Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
Ingestion:
Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. Call a physician.
Skin Contact:
In case of contact, wipe off excess material from skin then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Call a physician.
Eye Contact:
Immediately flush eyes with gentle but large stream of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Call a physician immediately.

5. Fire Fighting Measures

Fire:
Not considered to be a fire hazard. May form combustible fumes upon decomposition which may increase the flammability of a fire.
Explosion:
Reactions with incompatibles may pose an explosion hazard.
Fire Extinguishing Media:
Use any means suitable for extinguishing surrounding fire. Water spray may be used to keep fire exposed containers cool.
Special Information:
In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with

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(b)(4)

7.2 g/100 cc cold water; 20 g/100 cc hot water.
Density:
1.88
pH:
No information found.
% Volatiles by volume @ 21C (70F):
0
Boiling Point:
240C (464F) Decomposes.
Melting Point:
115C (239F)
Vapor Density (Air=1):
No information found.
Vapor Pressure (mm Hg):
No information found.
Evaporation Rate (BuAc=1):
No information found.

10. Stability and Reactivity

Stability:
Stable under ordinary conditions of use and storage.
Hazardous Decomposition Products:
May produce oxides of carbon and the contained metal.
Hazardous Polymerization:
Will not occur.
Incompatibilities:
Sodium hypobromite, acetylene, hydrazine, and nitromethane.
Conditions to Avoid:
Incompatibles.

11. Toxicological Information

Oral rat LD50: 710 mg/kg (monohydrate); oral rat LD50: 501 mg/kg (anhydrous).

```
--------\Cancer Lists\-----------------------------------------------------
                                        ---NTP Carcinogen---
Ingredient                              Known    Anticipated    IARC Category
```

(b)(4) --

12. Ecological Information

Environmental Fate:
This material is expected to significantly bioaccumulate. This material has an experimentally-determined bioconcentration factor (BCF) of greater than 100. Bioaccumulation data for copper.
Environmental Toxicity:
This material is expected to be very toxic to aquatic life. The LC50/96-hour values for fish are less than 1 mg/l. The IC50/72-hour values for algae are less than 1 mg/l. Toxicity data for copper.

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13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

(b)(4) [redacted]

15. Regulatory Information

--------\Chemical Inventory Status - Part 1\--------

Ingredient	TSCA	EC	Japan	Australia
(b)(4) [redacted]	Yes	Yes	Yes	Yes

--------\Chemical Inventory Status - Part 2\--------

Ingredient	Korea	--Canada-- DSL	NDSL	Phil.
(b)(4) [redacted]	Yes	Yes	No	Yes

--------\Federal, State & International Regulations - Part 1\--------

Ingredient	-SARA 302- RQ	TPQ	------SARA 313------ List	Chemical Catg.
(b)(4) [redacted]	No	No	No	Copper compo

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(b)(4) [redacted]

```
--------\Federal, State & International Regulations - Part 2\----------------
                                                      -RCRA-     -TSCA-
Ingredient                                   CERCLA   261.33      8(d)
(b)(4) [redacted] ---------- ------   ------     ------
                                             100      No         No

Chemical Weapons Convention:  No     TSCA 12(b):  No     CDTA:  No
SARA 311/312:  Acute: Yes      Chronic: Yes  Fire: No  Pressure: No
Reactivity: No          (Pure / Solid)
```

Australian Hazchem Code: None allocated.
Poison Schedule: None allocated.
WHMIS:
This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: **2** Flammability: **0** Reactivity: **0**
Label Hazard Warning:
DANGER! CAUSES EYE BURNS. HARMFUL IF SWALLOWED. CAUSES IRRITATION TO SKIN AND RESPIRATORY TRACT.
Label Precautions:
Do not get in eyes.
Avoid breathing dust.
Keep container closed.
Use with adequate ventilation.
Wash thoroughly after handling.
Avoid contact with skin and clothing.
Label First Aid:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. In case of skin contact, wipe any excess material off skin and then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. In all cases, get medical attention.
Product Use:
Laboratory Reagent.
Revision Information:
No Changes.
Disclaimer:
****
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(b)(4)

[redacted]

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THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT BAKER, INC. WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

****

Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)

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(b)(4)

[redacted]

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(b)(4) [redacted]

FIRST AID: SKIN: Wash exposed area with soap and water. If irritation persists, seek medical attention.

EYES: Wash eyes with plenty of water for at least 15 minutes, lifting lids occasionally. Seek Medical Aid. INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen

INGESTION: If swallowed, induce vomiting immediately after giving two glasses of water. Never give anything by mouth to an unconcious person.

Section 5 Fire Fighting Measures

Fire Extinguisher Type:	Water spray, Carbon dioxide, dry chemical, powder, foam.
Fire/Explosion Hazards:	None Known.
Fire Fighting Procedure:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and clothing.

Flash Point:	N/A	Upper Flamm. Limit in Air:	Not applicable

Section 10 Stability and Reactivity Information

Stability: Stable Conditions to Avoid: Temperature extremes

Materials to Avoid:
Strong oxidants, oleum

Hazardous Decomposition Products:
[redacted] (b)(4)

Condition to Avoid:None known

Section 11 Additional Information

Effects of overexposure, Acute and Chronic: Ingestions of large amounts can produce stomach cramps, stricture of esophagus, nausea, emesis. Contact with skin may have drying effect and cause irritation, redness and pain. May cause irritation and dryness to eyes. If inhaled, may cause irritation to lungs. Conditions aggravated/target organs: Persons with pre-existing eye, skin or respiratory conditions may be more susceptible.

DOT Classification: Not Regulated

DOT regulations may change from time to time. Please consult the most recent version of the relevant regulations.

Revision No:0 Date Entered: 9/1/2006 Approved by: WPF

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(b)(4)

[redacted]

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(b)(4) [redacted]

(b)(4) [redacted]

Ingestion	Wash out mouth with water. Drink plenty of water.
Advice for the doctor	Symptomatic treatment
Further information	See section 16 of MSDS

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents	Waterspray, foam, powder, carbon dioxide.
Restrictions	No restrictions.
Fire/explosion hazard	None
Main combustion gas	Carbon, nitrogen and sulfur oxides
Personal protection	Self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal protection	Gloves, respiratory protection.
Environmental precautions	No special precautions
Spillage procedure	Damp down. Avoid dust. Scoop into marked containers for disposal as chemical waste. Flush residues away with water.

7. HANDLING AND STORAGE

Handling

Occupational hygiene	Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Storage

Fire precautions	No special measures required
Storage facilities	Store in a cool, dry area with adequate ventilation
Segregation	Keep away from alkali.
Storage conditions	Keep containers closed.
	Sensitive to heat over 40 °C.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits None. Ensure adequate ventilation

Exposure Controls

Occupational exposure controls

General Personal Protection	Gloves, respiratory protection.
Hand protection	Chemical resistant protective gloves (EN 374).
	Recommended: permeation time >30 min. (level 2), material e.g. butyl or neopren.
	Observe glove manufacturers instructions.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Appearance

Form	Powder
Colour	Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) [redacted]

(b)(4) [redacted]

Odour	None	

Important health safety and environmental information

pH	5 - 5.5	20 g/l
Boiling point	Not applicable	
Flash point	Not applicable	
Oxidising properties	None	
Solubility in water	80 g/l	at 30 °C
	80 g/l	90 °C

Other information

Melting point	> 250 °C	
Bulk density	657 kg/m3	
Thermal decomposition	230 °C	
Ignition temperature	480 °C	BAM

10. STABILITY AND REACTIVITY

Conditions to avoid	None.
Materials to avoid	None
Hazardous decomposition products	None under normal storage conditions

11. TOXICOLOGICAL INFORMATION

Acute toxicity			
- LD50 oral	> 2000 mg/kg	Rat	
Primary irritation			
(Skin)	Non-irritant	Rabbit	
(Eye)	Non-irritant	Rabbit	
Skin sensitisation	Sensitizing	Guinea Pig	OECD 406
Adverse effects in man	See 16 in MSDS		
Additional information			

12. ECOLOGICAL INFORMATION

Ecotoxicity

Bacterial toxicity			
	IC50	> 300 mg/l	3 hour
Fish toxicity	LC0	100 mg/l	48 hour Golden orfe
	LC50	> 100 mg/l	
Summary		Not toxic or harmful to aquatic organisms	

Persistance and degradability

Bioelimination	10-25%, DOC Analysis.	OECD 302B
Summary	Poorly eliminated by adsorption on effluent treatment sludge	
Behaviour in treatment plants	No inhibition. No nitrification inhibition known.	

Additional Ecology Data

Phosphorus content	0 %	
Organohalogen content	0 %	
Metal content	2.04 %	Copper as organo-metal complex

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) [redacted]

(b)(4) [redacted]

Tested material	Standardised product
Additional information	

13. DISPOSAL CONSIDERATIONS

Product disposal	Incineration, landfill. Observe local regulations.
Contaminated packaging	Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

KEEP AWAY FROM FOODSTUFFS

Not classified as dangerous goods

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Symbol and classification	Xi : Irritant
R-Phrases	R43 : May cause sensitisation by skin contact
S-Phrases	S22 : Do not breathe dust
	S24 : Avoid contact with skin
	S37 : Wear suitable gloves
Contains	C.I. Reactive Blue 21
EU Guideline	99/45

16. OTHER INFORMATION

Cases of respiratory sensitisation have been observed with reactive dyes.

Care should be taken to avoid inhalation.

Should an individual become sensitized a physician should be consulted and all contact with reactive dyes must cease immediately.

List of relevant R-phrases (Section 2)

R43 : May cause sensitisation by skin contact

Recommended restrictions on use

Huntsman textile, paper and leather dyes and chemicals are technical grade and unless otherwise stated or agreed are recommended only for industrial use in applications involving the pretreatment dyeing or finishing of textiles, paper or leather. Other intended uses including their use in consumer products governed by specific legislation or standards should be referred to the manufacturer. The data contained in the SDS apply only to Huntsman products sold under the stated trade names. Technical information in support will be provided by Huntsman at the request of competent authorities.

member of ETAD

MSDS Changes	15. REGULATORY INFORMATION S-Phrases

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 428

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(b)(4)

[redacted]

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(b)(4) [redacted]

least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.

Skin Contact:
Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: OPEN CUP: 79°C (174.2°F).

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO2).

Fire Hazards in Presence of Various Substances:
Flammable in presence of open flames and sparks, of heat.
Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available.
Slightly explosive in presence of open flames and sparks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 430

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) [redacted]

on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. est. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, metals, acids, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Powdered solid. Amorphous solid powder.)

Odor: Odorless.

Taste: Not available.

Molecular Weight: (44.05)n g/mole

Color: Off-white. White. Colorless.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point:
Softens at about 200°C (392°F) with decomposition.
Decomposition @ 228 deg. C.

Critical Temperature: Not available.

Specific Gravity: 1.19-1.31(Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) [redacted]

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility:
Soluble in cold water, hot water.
Insoluble in diethyl ether, acetone, petroleum solvents, aromatic hydrocarbons, esters.
Practically insoluble in animal and vegetable oils and chlorinated hydrocarbons.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Heat, ignition sources, flame, excess dust generation, incompatible materials.

Incompatibility with various substances: Reactive with oxidizing agents, metals, acids, alkalis.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Incompatible with oxidizing agents (perchlorates, nitrates, etc.), reactive metals (sodium, calcium, zinc, etc.), sodium or calcium hypochlorite, materials reactive with hydroxyl compounds. Reaction with peroxides may result in violent decomposition of peroxide possibly creating and explosion.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation, Ingestion.

Toxicity to Animals:
Acute oral toxicity (LD50): 14700 mg/kg [Mouse].
Acute oral toxicity (LD50): > 20000 mg/kg [Rat].

Chronic Effects on Humans: CARCINOGENIC EFFECTS: 3 (Not classifiable for human.) by IARC.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: May cause cancer (tumorigenic) based on animal studies. No human data found at this time.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects:
Skin: May cause skin irritation.
Eyes: May cause eye irritation.
Ingestion: May cause gastrointestinal (digestive) tract irritation. May affect behavior/central nervous system (symptoms may include general depressed activity, altered sleep time, muscle weakness). May also affect blood and metabolism.
Inhalation: May cause respiratory tract irritation.
Chronic Potential Health Effects:
Inhalation or ingestion for prolonged period of time may affect blood and metabolism, and behavior.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 452

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(b)(4) [redacted]

May cause cancer (tumorigenic) based on animal studies. No human data found at this time.

Section 12: Ecological Information

(b)(4) [redacted]

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) [redacted]

Flammability: 2

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves.
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent.
Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/10/2005 08:47 PM

Last Updated: 11/06/2008 12:00 PM

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(b)(4) [redacted]

Fisher Scientific

Material Safety Data Sheet
Tween® 20

MSDS# 01992

Section 1 - Chemical Product and Company Identification

MSDS Name:	Tween® 20
Catalog Numbers:	AC233360000, AC330190000, AC330195000, 23336-0010, 23336-2500
Synonyms:	Polyoxyethylene(20)sorbitan monolaurate.
Company Identification:	Fisher Scientific One Reagent Lane Fair Lawn, NJ 07410
For information in the US, call:	201-796-7100
Emergency Number US:	201-796-7100
CHEMTREC Phone Number, US:	800-424-9300

Section 2 - Composition, Information on Ingredients

CAS#:	9005-64-5
Chemical Name:	Tween® 20
%:	100
EINECS#:	unlisted

Hazard Symbols:	None listed
Risk Phrases:	None listed

Section 3 - Hazards Identification

EMERGENCY OVERVIEW

Caution! The toxicological properties of this material have not been fully investigated. May cause eye, skin, and respiratory tract irritation. Target Organs: None known.

Potential Health Effects

Eye:	May cause eye irritation.
Skin:	May cause skin irritation. May be harmful if absorbed through the skin.
Ingestion:	May cause irritation of the digestive tract. May be harmful if swallowed.
Inhalation:	May cause respiratory tract irritation. May be harmful if inhaled.
Chronic:	No information found.

Section 4 - First Aid Measures

Eyes:	Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. If irritation develops, get medical aid.
Skin:	Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical aid if irritation develops or persists.
Ingestion:	Do not induce vomiting. Get medical aid if irritation or symptoms occur.
Inhalation:	Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid if cough or other symptoms appear.
Notes to Physician:	

Section 5 - Fire Fighting Measures

General Information:	As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.
Extinguishing Media:	Use water spray, dry chemical, carbon dioxide, or chemical foam.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) [redacted]

Autoignition Temperature: Not available

Flash Point: > 150 deg C (> 302.00 deg F)

Explosion Limits: Lower: Not available

Explosion Limits: Upper: Not available

NFPA Rating: health: 1; flammability: 1; instability: 0;

Section 6 - Accidental Release Measures

General Information: Use proper personal protective equipment as indicated in Section 8.

Spills/Leaks: Absorb spill with inert material (e.g. vermiculite, sand or earth), then place in suitable container. Provide ventilation. Do not let this chemical enter the environment.

Section 7 - Handling and Storage

Handling: Use with adequate ventilation. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation.

Storage: Store in a cool, dry place. Store in a tightly closed container. Store at around 20°C.

Section 8 - Exposure Controls, Personal Protection

Chemical Name	ACGIH	NIOSH	OSHA - Final PELs
(b)(4) [redacted]	none listed	none listed	none listed

(b)(4) [redacted]

Engineering Controls:

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.

Exposure Limits

Personal Protective Equipment

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin: Wear appropriate protective gloves to prevent skin exposure.

Clothing: Wear appropriate protective clothing to prevent skin exposure.

Respirators: A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149 must be followed whenever workplace conditions warrant respirator use.

Section 9 - Physical and Chemical Properties

Physical State: Viscous liquid

Color: clear yellow to amber

Odor: Not available

pH: 6 (10% aq.sol.)

Vapor Pressure: Not available

Vapor Density: Not available

Evaporation Rate: Not available

Viscosity: 400 mPa @ 50 deg C

Boiling Point: > 100 deg C @ 760 mmHg (> 212.00°F)

Freezing/Melting Point: Not available

Decomposition Temperature: Not available

Solubility in water: 100 g/L

Specific Gravity/Density: 1.100

Molecular Formula:

Molecular Weight:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) [redacted]

Section 10 - Stability and Reactivity

Chemical Stability:	Stable under normal temperatures and pressures.
Conditions to Avoid:	Incompatible materials, excess heat.
Incompatibilities with Other Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Carbon monoxide, carbon dioxide.
Hazardous Polymerization	Has not been reported.

Section 11 - Toxicological Information

RTECS#: (b)(4) [redacted])

RTECS:

LD50/LC50: (b)(4) [redacted]

(b)(4) [redacted] carcinogen by ACGIH, IARC, NTP, or CA Prop 65.

Epidemiology:	No information found
Teratogenicity:	Teratogenic effects have occurred in experimental animals.
Reproductive:	Adverse reproductive effects have occurred in experimental animals.
Neurotoxicity:	No information found
Mutagenicity:	No information found
Other:	See actual entry in RTECS for complete information.

Section 12 - Ecological Information

Other: Do not empty into drains.

Section 13 - Disposal Considerations

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification. RCRA P-Series: None listed. RCRA U-Series: None listed.

Section 14 - Transport Information

US DOT
Shipping Name: Not regulated.
Hazard Class:
UN Number:
Packing Group:
Canada TDG
Shipping Name: Not regulated as a hazardous material
Hazard Class:
UN Number:
Packing Group:

Section 15 - Regulatory Information

US Federal

TSCA

(b)(4) [redacted]

Inventory.

Health & Safety Reporting List	None of the chemicals are on the Health & Safety Reporting List.
Chemical Test Rules	None of the chemicals in this product are under a Chemical Test Rule.
Section 12b	None of the chemicals are listed under TSCA Section 12b.
TSCA Significant New Use Rule	None of the chemicals in this material have a SNUR under TSCA.
CERCLA Hazardous Substances and	None of the chemicals in this material have an RQ.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) [redacted]

corresponding RQs	
SARA Section 302 Extremely Hazardous Substances	None of the chemicals in this product have a TPQ.
Section 313	No chemicals are reportable under Section 313.
Clean Air Act:	This material does not contain any hazardous air pollutants. This material does not contain any Class 1 Ozone depletors. This material does not contain any Class 2 Ozone depletors.
Clean Water Act:	None of the chemicals in this product are listed as Hazardous Substances under the CWA. None of the chemicals in this product are listed as Priority Pollutants under the CWA. None of the chemicals in this product are listed as Toxic Pollutants under the CWA.
OSHA:	
STATE	(b)(4) [redacted] present on state lists from CA, PA, MN, MA, FL, or NJ.
California Prop 65	
California No Significant Risk Level:	None of the chemicals in this product are listed.

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols:Not available

Risk Phrases:

Safety Phrases:

S 24/25 Avoid contact with skin and eyes.

WGK (Water Danger/Protection)

(b)(4) [redacted]

Canada

(b)(4) [redacted]

Canadian WHMIS Classifications: Not available

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by those regulations.

(b)(4) [redacted] not listed on Canada's Ingredient Disclosure List.

Section 16 - Other Information

MSDS Creation Date: 12/11/1997

Revision #5 Date 11/29/2007

Revisions were made in Sections: 3, 4, 5, 6, 7, 8, 9, 10, 11, 1

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantibility or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential, or exemplary damages howsoever arising, even if the company has been advised of the possibility of such damages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Filligent (HK) Limited
C/O Mr. Ian Gordon
Emergo Group, Incorporated
611 West 5th Street Third Floor
Austin, Texas 78701

MAY 26 2011

Re: K101128
Trade/Device Name: BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: OUK
Dated: May 20, 2011
Received: May 23, 2011

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

4 Indications for Use Statement

510(k) Number:

K101128.

Device Name:

BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A

Indications for Use:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks inactivate 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007,A/Wisconsin/67/2005,), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

Prescription Use _____ (21 CFR 801 Subpart D) AND/OR Over-The Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K101128

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 3

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There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded and expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of microorganisms, body fluids and particulate material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 4

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 23, 2011

FILLIGENT LIMITED
C/O EMERGO GROUP
611 WEST 5TH STREET
THIRD FLOOR
AUSTIN, TEXAS 78701
ATTN: IAN GORDON

510k Number: K101128

Product: BIOFRIEND BIOMASK SURGICAL FAC

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 16, 2011

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY
SUITE 500
AUSTIN, TEXAS 78746
ATTN: IAN GORDON

510k Number: K101128

Product: BIOFRIEND BIOMASK SURGICAL FAC

Extended Until: 07/21/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent
creating
global health choices

May 13, 2011

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAY 16 2011
Received

Re: Request for Extension of Time to Respond to Additional Information Request

510(k) Premarket Notification – K101128

Filligent (HK) Limited ("Filligent") respectfully asks for an extension of time in order to respond to FDA email correspondence dated March 8 and March 16, 2011, placing on hold our 510(k) Premarket Notification pending receipt of the additional information requested by the Office of Device Evaluation, on March 8 and March 16, 2011.

Filligent respectfully requests an additional forty-five (45) days, from the date hereof, to respond to the FDA's request for additional information.

Should you require additional information as to this, please do not hesitate to contact us at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely,

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

K38

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 14, 2011

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY
SUITE 500
AUSTIN, TEXAS 78746
ATTN: IAN GORDON

510k Number: K101128

Product: BIOFRIEND BIOMASK SURGICAL FAC

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 08, 2011

510k Number: K101128

Product: BIOFRIEND BIOMASK SURGICAL FAC

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY
SUITE 500
AUSTIN, TEXAS 78746
ATTN: IAN GORDON

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5019; Released by CDRH on 06-06-2016

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

February 22, 2011

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY
SUITE 500
AUSTIN, TEXAS 78746
ATTN: IAN GORDON

510k Number: K101128

Product: BIOFRIEND BIOMASK SURGICAL FAC

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 19, 2011

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY SUITE 500
AUSTIN, TEXAS 78746
UNITED STATES
ATTN: IAN GORDON

510k Number: K101128
Product: BIOFRIEND BIOMASK SURGICAL FAC

Extended Until: 03/29/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent
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global health choices

January 13, 2011

FDA CDRH DMC

JAN 18 2011

Received

K-76

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Request for Extension of Time to Respond to Additional Information Request

510(k) Premarket Notification – K101128

Filligent (HK) Limited ("Filligent") respectfully asks for an extension of time to respond to the official FDA fax, dated December 29, 2011, requesting further additional information. This most recent request for information was generated on completion of the FDA's review of additional information submitted by Filligent on November 13, 2010.

Filligent respectfully requests an additional forty-five (45) days, from the date hereof, to respond to the FDA's request for additional information.

Should you require additional information as to this, please do not hesitate to contact us at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely,

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 04, 2011

510k Number: K101128
Product: BIOFRIEND BIOMASK SURGICAL FAC

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY SUITE 500
AUSTIN, TEXAS 78746
UNITED STATES
ATTN: IAN GORDON

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 175

Records processed under FOIA Request #2015-6019; Released by CDRH on 06-06-2016

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 12, 2010

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY SUITE 500
AUSTIN, TEXAS 78746
UNITED STATES
ATTN: IAN GORDON

510k Number: K101128

Product: BIOFRIEND BIOMASK SURGICAL FAC

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 05, 2010

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY SUITE 500
AUSTIN, TEXAS 78746
UNITED STATES
ATTN: IAN GORDON

510k Number: K101128
Product: BIOFRIEND BIOMASK SURGICAL FAC

Extended Until: 11/15/2010

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent
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K101128

August 3, 2010

Received
AUG 05 2010
FDA CDRH DMC

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Request for Extension of Time to Respond to AI Letter

510(k) Premarket Notification – K101128

Filligent (HK) Limited ("Filligent") respectfully asks for a further extension of time to respond to the official FDA letter (the "AI letter") dated May 21, 2010 requesting additional information.

An initial extension of 90 days was granted to Filligent on June 21, 2010 until August 19, 2010. Filligent requests an additional ninety (90) days to respond to the FDA's request for additional information.

Should you require additional information as to this, please do not hesitate to contact us at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

K-12

Sincerely,

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DMC at CDRHREFORMSTATUS@fda.hhs.gov or call 301-796-8118.

237

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 21, 2010

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY SUITE 500
AUSTIN, TEXAS 78746
UNITED STATES
ATTN: IAN GORDON

510k Number: K101128
Product: BIOFRIEND BIOMASK SURGICAL FAC

Extended Until: 08/19/2010

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center ¿ WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 21, 2010

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY SUITE 500
AUSTIN, TEXAS 78746
UNITED STATES
ATTN: IAN GORDON

510k Number: K101128

Product: BIOFRIEND BIOMASK SURGICAL FAC

Extended Until: 07/20/2010

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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June 18, 2010

FDA CDRH DMC
JUN 2 1 2010
Received
6-29

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Request for Extension of Time to Respond to AI Letter

510(k) Premarket Notification – K101128

Filligent (HK) Limited ("Filligent") respectfully asks for an extension of time to respond to the official FDA letter (the "AI letter") dated May 21, 2010 requesting additional information. As a result of an administrative oversight the AI letter sent by mail to Filligent via its regulatory consultants in the USA was not received by Filligent until June 17, 2010. Consequently, Filligent requests an additional thirty (30) days to respond to the FDA's request for additional information.

Should you require additional information as to this, please do not hesitate to contact us at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely,

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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June 18, 2010

FDA CDRH DMC
JUN 21 2010
Received
1240

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Request for Extension of Time to Respond to AI Letter

510(k) Premarket Notification – K101128

Filligent (HK) Limited ("Filligent") respectfully asks for an extension of time to respond to the official FDA letter (the "AI letter") dated May 21, 2010 requesting additional information. As a result of an administrative oversight the AI letter sent by mail to Filligent via its regulatory consultants in the USA was not received by Filligent until June 17, 2010. Consequently, Filligent requests an additional thirty (30) days to respond to the FDA's request for additional information.

Should you require additional information as to this, please do not hesitate to contact us at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely,

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 21 2010

Filligent (HK) Limited
C/O Ms. Ian Gordon
Chief Executive Officer
Emergo Group, Incorporated
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

Re: K101128
Trade Name: BioFriend BioMask
Dated: April 20, 2010
Received: April 22, 2010

Dear Ms. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require additional effectiveness and safety testing information on the subject device. We also require additional general/administrative information on the subject device and clarifications in the labeling of the device.

The deficiencies listed on the following pages are organized into different sections. We request that you carefully review these deficiencies before you formulate your responses.

Also, please be advised that we may have additional concerns regarding your labeling and indications for use statement after we receive additional information on this submission from you.

We understand that the preparation of a 510(k) submission for a new type of device such as the BioFriend™ BioMask™ can be a complex undertaking. You may find it helpful to discuss the deficiencies listed below with the FDA, to understand what information is being requested and the means by which you can respond to the deficiencies. The Division would be happy to discuss this with you either by teleconference or in a face to face meeting, whichever is more convenient for you.

To schedule a meeting or a teleconference with FDA, please contact Steven Elliott, M.S., Reviewer, Infection Control Devices Branch at (301) 796-5285 or by email at steven.elliott@fda.hhs.gov.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

To complete the review of this submission, we ask that you address the deficiencies listed in this letter and provide the additional information requested. Please provide an item-wise response to each deficiency.

Administrative:

1. You provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard. Please provide a new Standards Data Report for 510(k)s form for this standard that cites conformance to ISO 10993-10:2002. This form can be found at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf

2. You provided a 510(k) summary that did not contain an adequate description of the subject device. You did not indicate the subject device models or explain the differences between all subject models intended for clearance. Please provide an amended 510(k) summary that lists the model numbers of all devices intended for clearance in this submission and explains all differences between all device models and predicates. Please ensure that the amended 510(k) summary addresses all related deficiencies in this memorandum.

Device Description:

3. You have stated that Citric acid lowers the pH of its environment, but did not indicate the pH on the exterior surface of the mask, or the pH required for the claimed deactivation of specific influenza strains. This information is required to effectively determine the antimicrobial effect of Citric Acid on the mask surface. Please indicate the pH on the exterior surface of the mask, explain how this pH was determined and provide acceptance criteria (include pH range) for the pH of the mask exterior.

4. You have described Both BioFriend™ BioMask™ devices as having anti-viral activity against influenza A and B strains. However, the relative roles of the three potentially antiviral compounds are not clearly delineated and the minimal inhibitory concentration (MEC) of the antimicrobial agents is not provided. Please describe the specific mode of action (state both the target molecule on the influenza virus and suppression/denaturing interaction with specific antimicrobial agent) and identify the magnitude of the contribution of the antimicrobial effect for each agent.

5. You did not provide the minimal effective concentration (MEC) of (b)(4) [redacted] (b)(4) [redacted] This information is necessary to determine if the subject masks contain enough of the agents to ensure the intended antimicrobial performance. Please provide the MEC values for the claimed antimicrobial agents: (b)(4) [redacted] (b)(4) [redacted]

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6. Please provide data to support the statement that both the viral inoculum and the citric acid on the surface of the mask are actually drawn into the inner layers of the mask during testing and use. Please provide the pH achieved in the second layer of the mask during challenge testing.

Indication for Use

7. You provided an Indication for Use (IFU) statement that did not list the model numbers of the subject device. You should clearly specify all device models and state their respective model numbers. Please provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. Please include a description of the differing features between model numbers.

8. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007. Please revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

9. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures." Please revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

10. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only." Please remove the above statement from the IFU as testing to support such claim is not provided in the submission.

11. The Indication for Use (IFU) statement did not list the influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask. Please include the influenza virus strains that have been shown to be adequately reduced (≥4 log reduction) by the activity of the mask in the IFU statement.

12. Please ensure that the revised IFU statement addresses all listed deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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Labeling:

13. You provided labeling that makes broad claims about the performance of the device against influenza viruses. These claims include but are not limited to: "Inactivation of 99.99% of H1N1 influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of all influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim. Please provide labeling that only includes antiviral performance claims on virus strains that demonstrated a 4 $\log_{10}$ or greater reduction during in-vitro testing.

14. You provided labeling with the claim: "Kills influenza Viruses on Contact." This claim implies an instantaneous inactivation of influenza which has not been substantiated. Please remove the claim: "Kills influenza Viruses on Contact" from all labeling.

15. You provided labeling with the claim: "BioMask™ kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file. Please revise the above labeling claim to accurately reflect the performance data.

16. You included the Indication for Use (IFU) statement in the labeling. Deficiencies 7 - 11 address the IFU related deficiencies. Please revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiencies 7 – 11.

17. The statement: "HOW IT WORKS: The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported by performance data. Please provide supporting data or revise/remove this claim.

18. Please include the following statement in the device labeling: "No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from influenza infection."

19. The online brochure contains numerous claims associated with the BioMask device that appears to be the subject of the submission. These claims are not substantiated by data in this 510(k) submission. The claims include:

BioFriend's revolutionary, patented technology traps and kills bacteria and viruses on contact AND allows you to breathe normally:

- Traps and kills 99.9% of harmful germs
- Superior breathability & comfort
- Self-sanitizing for ALL-DAY WEAR

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 353

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 354

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of the copper, two-thirds of the zinc and one fourth of the citric acid present in the BioMask could be lost to leaching. This information creates concerns over both the safety and efficacy of the subject device. Please explain how the broad acceptance criteria relate to the minimal effective concentrations of (b)(4) [redacted]. In addition, please provide justification ensuring the safety and efficacy of the subject device with the variability in antiviral agents and high levels of leaching that have been reported in the submission.

26. Please indicate how many different lots of product were used in the safety testing. FDA is concerned about whether the broad acceptance criteria for the antimicrobial components of this device are contributing to the results. Please address this concern by providing test data and scientific justification.

(b)(4) [redacted]

This discussion should include consideration of the effects of repeated exposures in the course of a work day. Even if its toxicity is not excessive, the effect may be at least unpleasant to healthcare personnel who wear this device repeatedly in the course of a day or for prolonged periods.

28. Please discuss the potential for toxicity for users of the subject device using toxicity data and recommended maximum exposure levels for humans rather than basing the toxicity conclusions on rat data alone. In addition, please provide justification that the worst case estimated losses in both the gas-off and simulated saliva testing are within appropriate safety levels for humans. All testing and discussion should take into consideration exposure routes under conditions of use of the device.

29. You did not provide a positive control for the primary skin irritation test. Positive controls are recommended in the ISO 10993-10:2002 should be provided to demonstrate the sensitivity of the assay. Please provide positive control data, performed to ISO 10993-10:2002 standards, that demonstrate the sensitivity of the irritation assay

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 355

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31. Please discuss the variable and borderline anti-influenza performance. Please explain whether this variable performance may be related to the wide acceptance criteria for the BioMask antimicrobial agent components, especially citric acid.

32. Please identify how many lots of product were used in the antiviral performance studies. FDA is concerned that the broad antiviral component specifications may contribute to the variable device performance demonstrated.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Forguidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at ***http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf***

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

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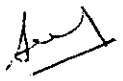
The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Steven Elliott at (301) 796-5285. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Geetha C. Jayan, Ph.D.
Branch Chief, Infection Control Devices Branch
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 357

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 22, 2010

FILLIGENT (HK) LIMITED
C/O EMERGO GROUP, INC.
1705 S. CAPITAL OF TEXAS HWY SUITE 500
AUSTIN, TEXAS 78746
UNITED STATES
ATTN: IAN GORDON

510k Number: K101128
Received: 4/22/2010
Product: BIOFRIEND BIOMASK SURGICAL FAC

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

K101128

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April 19, 2010

Document Mail Center – WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
APR 22 2010
Received

Re: 510(k) Premarket Notification

Our firm is submitting a traditional premarket notification for the following new device:

Trade Name(s):	BioFriend™ BioMask™ Surgical Facemask
	Models: Universal BF-200-2001 and Premium BF-200-3013
Classification Name:	Mask, Surgical
Classification Regulation:	878.4040
Panel:	General Hospital and Surgery
Product Code:	FXX

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

7th Floor, 69 Jervois Street, Sheung Wan, Hong Kong
t: (852) 2542 2400 f: (852) 2542 2411 www.filligent.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at:

Filligent (HK) Limited
7th Floor 69 Jervois Street
Sheung Wan
Hong Kong
Telephone: +852 2542 2400
Facsimile: +852 2542 2411
Email: melissa@filligent.com

Regards,

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Filligent (HK) Limited

510 (K) PRE-MARKET
NOTIFICATION for

BIOFRIEND™ BIOMASK™
SURGICAL FACEMASK

CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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1 Medical Device User Fee Cover Sheet

The Medical Device User Fee Cover Sheet is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

FILLIGENT HK LIMITED
7/F 69 Jervois Street
Sheung Wan
Hong Kong
HK

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Theodore Brun

2.1 E-MAIL ADDRESS
theo.brun@filligent.com

2.2 TELEPHONE NUMBER (include Area code)
+852 9313 0972

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
+852 2542 2411

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted]

10-Mar-2010

Form FDA 3601 (01/2007)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

2 CDRH Premarket Review Submission Cover Sheet

The CDRH Premarket Review Submission Cover Sheet is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
04/20/2010	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Filligent (HK) Limited	Establishment Registration Number *(if known)* Hong Kong Company Registration Number 1000163
Division Name *(if applicable)*	Phone Number *(including area code)* +852 2542 2400
Street Address 7 Floor 69 Jervois Street	FAX Number *(including area code)* +852 2542 2411

City	State / Province	ZIP/Postal Code	Country
Hong Kong	N/A	N/A	Hong Kong

Contact Name Melissa Mowbray-d'Arbela	
Contact Title Chief Executive Officer	Contact E-mail Address melissa@filligent.com

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name Emergo Group, Inc	
Division Name *(if applicable)* N/A	Phone Number *(including area code)* +512 327 9997
Street Address 1705 S Capital of Texas Highway, Suite 500	FAX Number *(including area code)* +512 327 9998

City	State / Province	ZIP Code	Country
Austin,	Texas	78746	USA

Contact Name Ian Gordon	
Contact Title Senior Vice President	Contact E-mail Address igordon@emergogroup.com

PSC Graphics (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FXX	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K061864	1	Non Sterile Surgical Mask	1	Dukal Corporation
2	K061716	2	Prestige Ameritech Face Mask	2	Prestige Ameritech
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

BioFriend BioMask Surgical Face Mask

	Trade or Proprietary or Model Name for This Device		Model Number
1	BioFriend™ BioMask™ Surgical Facemask, Premium	1	BF-200-3013
2	BioFriend™ BioMask™ Surgical Facemask, Universal	2	BF-200-2001
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 C080073	2 I090448/S001	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: FXX

C.F.R. Section *(if applicable)*: 21 CFR 878.4040

Classification Panel: GENERAL & PLASTIC SURGERY REVIEW PANEL

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications *(from labeling)*

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	F2100-07	ASTM International	Standard Specification for Performance of Materials Used in Medical Face Masks	2007	
2	F2101-07	ASTM International	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus	2007	
3	F1862-07	ASTM International	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	2007	
4	F2299-03	ASTM International	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres.	2003	
5	16 CFR 1610	Federal Government	Standard for the Flammability of Clothing Textiles	2009	
6	MIL-M-36954C	U.S. Department of Defense	Military Specification, Mask, Surgical, Disposable		06/12/1975
7	10993-10	International Organization for Standardization	Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity	Second Edition	09/01/2002

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	10993-18	International Organization for Standardization	Biological evaluation of medical devices -- Part 18. Chemical characterization of materials	First Edition	07/01/2005
2	ASTM E 1052-96	American Society for Testing and Materials	Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension	2002	
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

3 510(k) Cover Letter

The 510(k) Cover Letter is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent
creating
global health choices

April 19, 2010

Document Mail Center – WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: 510(k) Premarket Notification

Our firm is submitting a traditional premarket notification for the following new device:

Trade Name(s):	BioFriend™ BioMask™ Surgical Facemask
	Models: Universal BF-200-2001 and Premium BF-200-3013
Classification Name:	Mask, Surgical
Classification Regulation:	878.4040
Panel:	General Hospital and Surgery
Product Code:	FXX

Design and Use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

7th Floor, 69 Jervois Street, Sheung Wan, Hong Kong
t: (852) 2543 2409 f: (852) 2543 2411 www.filligent.com
Questions? Contact FDA/CDRH/OCE/DIB at CDRHFOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at:

Filligent (HK) Limited
7th Floor 69 Jervois Street
Sheung Wan
Hong Kong
Telephone: +852 2542 2400
Facsimile: +852 2542 2411
Email: melissa@filligent.com

Regards,

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

4 Indications for Use Statement

510(k) Number (if known):

Device Name:

BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001 and Premium BF-200-3013

Indications for Use:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as during dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

Prescription Use _____ AND/OR Over-The Counter Use ___X___
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

7th Floor, 69 Jervois Street, Sheung Wan, Hong Kong
t: (852) 2543 2409 f: (852) 2543 2411 www.filligent.com

Questions? Contact FDA/CDRH/OCE/DIB at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5 510(k) Summary

5.1 Applicant and Correspondent

Name: Filligent (HK) Limited

Address: 7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

Contact Person: Melissa Mowbray-d'Arbela
Chief Executive Officer

Phone: (852) 2542 2400

Date of Preparation: April 20, 2010

5.2 Manufacturer

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

5.3 Name of Device

Trade/Proprietary/Model Name: BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001
Premium BF-200-3013

Common Name: Surgical Facemask

Classification Name: Mask, Surgical

Classification Regulation: 878.4040

Panel: General Hospital

Product Code: FXX

Recognized Performance Std: ASTM F2100-07 (refer to submission)

5.4 Devices to Which New Device is Substantially Equivalent

Device Name: Prestige Ameritech Face Mask
Manufacturer: Prestige Ameritech
Reference: K061716

Questions? Contact FDA/CDRH/OCE/DIB at CDRHFOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.5 Device Description

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical face masks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second layer is treated so as to inactivate viruses. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip.

5.6 Statement of Intended Use

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as during dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

5.7 Summary of Technological Characteristics

The BioFriend™ BioMask™ surgical facemasks have the same filter and barrier properties as the predicate device, and conform to the recognized FDA consensus standard ASTM F2100-07 Standard Specification for Performance of Materials used in Medical Face Masks. The outer layer of both models is coated with a hydrophilic plastic which draws aerosol droplets through to an inner layer which has been treated so as to inactivate viruses. Laboratory test results demonstrate that within 5 minutes of contact with the surface of the masks, the BioFriend™ BioMask™ surgical facemasks inactivate 99.99% of 18 different sub-types of Influenza A and B viruses, including the circulating H1N1, recent vaccine isolates, major reassortments and avian and animal (equine and swine) isolates.

The BioFriend™ BioMask™ surgical facemasks have been tested for and pass standardized tests for fluid penetration resistance, particulate filtration efficiency, bacterial filtration efficiency, flammability, and breathing resistance. The device as a whole has been demonstrated to be biocompatible by irritation, sensitization and extractable testing.

7th Floor, 69 Jervois Street, Sheung Wan, Hong Kong
t: (852) 2543 2409 f: (852) 2543 2411 www.filligent.com
Questions? Contact FDA/CDRH/OCE/DIB at CDRHFOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

The materials of construction use in the BioFriend™ BioMask™ surgical facemask are equivalent to those of the predicate device. The device as a whole is substantially equivalent to the predicate.

5.8 Brief description of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

- Bacterial Filtration Efficiency – ASTM F2101
- Sub-micron Particulate Filtration Efficiency – ASTM F2299
- Fluid Penetration Resistance – ASTM F1862
- Breathing Resistance – MIL-M-3654C
- Flammability Testing – 16 CFR 1610
- Biocompatibility - Irritation – ISO 10993-10
- Biocompatibility - Sensitization – ISO 10993-10
- Biocompatibility – Chemical Characterization – ISO 10993-18

5.9 Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Not applicable.

5.10 Conclusions drawn from the nonclinical and clinical tests

The materials of construction used in both models of the BioFriend™ BioMask™ surgical facemask are substantially equivalent to those of the predicate device. The device as a whole has been demonstrated to be biocompatible by irritation and sensitization testing, and toxicological assessment of the product's ingredients potentially released with inhalation or salivary contact, and indicates that the product is safe for use in the intended application. Laboratory testing has demonstrated the product's efficacy. The BioFriend™ BioMask™ surgical facemask has been shown to be substantially equivalent to the predicate device.

7th Floor, 69 Jervois Street, Sheung Wan, Hong Kong
t: (852) 2543 2409 f: (852) 2543 2411 www.filligent.com
Questions? Contact FDA/CDRH/OCE/DIB at CDRHFOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

6 Truthful and Accuracy Statement

The Truthful and Accuracy Statement is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DIB at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Truthful and Accuracy Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Chief Executive Officer of Filligent (HK) Limited, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

April 20, 2010

(Date)

(Premarket Notification [510(k)] Number)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

7th Floor, 69 Jervois Street, Sheung Wan, Hong Kong
t: (852) 2542 2400 f: (852) 2542 2411 www.filligent.com

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

7 Class III Summary and Certification

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

8 Financial Certification or Disclosure Statement

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

9 Declarations of Conformity and Summary Reports

The Declarations of Conformity and Summary Reports are provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 6-198	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Surgical Masks - Premarket Notification [510(k)] Submissions

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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Department of Health and Human Services
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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2101-07 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materia

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 6-199		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
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Title of guidance: Surgical Masks - Premarket Notification [510(k)] Submissions

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STANDARD TITLE [1]

MIL-M-36954C, Military Specification: Mask, Surgical, Disposable June 12, 1975, Paragraph 4.4.1.2.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] #		
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STANDARD TITLE [1]

ASTM F2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☐	☑
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
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STANDARD TITLE [1]

ASTM F1862: 2007 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 6-184		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
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Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Surgical Masks - Premarket Notification [510(k)] Submissions

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STANDARD TITLE [1]

16 CFR Part 1610: Standard for the flammability of clothing textiles.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Surgical Masks - Premarket Notification [510(k)] Submissions

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STANDARD TITLE [1]

ISO 10993 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation - In vivo. 2003

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 2-87		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☑
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation - In vivo. 2003

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation Test	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

6.3 Animal skin irritation test

DESCRIPTION

An assessment is made of the potential of the material under test to produce dermal irritation in a relevant animal model

JUSTIFICATION

Existing data for predicate devices and other similiar marketed devcies allows for comparative evaluation

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.0	Irritation Test	☐ Yes ☑ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

6.4 Human skin irritation test

DESCRIPTION

An assessment is made of potential of the material under test to cause human cutaneous irritation

JUSTIFICATION

Frequently used for chemicals to which human exposure is high, typically detergents and cosmetics

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed Hypersensitivity Tests	☐ Yes ☑ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

7.4 Maximization test for delayed hypersenstivity

DESCRIPTION

An assessment is made of the potential of the material under test to produce skin sensitization in guinea pigs

JUSTIFICATION

Method prefered for single chemicals.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation - In vivo. 2003

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed Hypersensitivity Tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

7.5 Closed-patch test for delayed hypersensitivity

DESCRIPTION

An assessment is made of the potential of the material under test to produce skin sensitization in guinea pigs

JUSTIFICATION

Existing data for predicate devices and other similiar marketed devcies allows for comparative evaluation

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE [1]

ISO 10993-18 Biological evaluation of medical devices - Part 18: Chemical characterization of materials

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] #		
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Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM E 1052-96 Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☑
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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Appendix 9

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10 Executive Summary

10.1 Description

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical face masks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second layer is treated with copper and zinc. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip. One model is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard “comfort” features such ear adjusters and an anti-fog nose insert.

10.2 Indications for Use

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as during dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

10.3 Technological Characteristics

21 CFR 807.92 requires any new device to be “substantially equivalent” to a current legally marketed device from the same class. As indicated by the FDA/CDRH on October 10, 2008 in its 513(g) response letter to Filligent, the relevant class for both models of the BioFriend™ BioMask™ surgical facemask is a Class II Surgical Face Mask. The Class II Surgical Face Mask predicate chosen for the BioFriend™ BioMask™ surgical facemasks is the current and legally marketed Prestige Ameritech Facemask (K061716).

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11 Device Description

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11.1 Summary Description

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical face masks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second layer is treated with copper and zinc. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip. One model is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard “comfort” features such ear adjusters and an anti-fog nose insert.

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11.2 Indications for Use

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

11.3 Detailed Device Description

11.3.1 Performance

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. One is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard “comfort” features such ear adjusters and an anti-fog nose insert. As such the two mask models are identical for testing purposes. All performance tests were conducted on the final finished device for the Premium BF-200-3013 model. We therefore believe it is reasonable to ascribe the same performance results to the Universal BF-200-2001 model as shape does not affect the relevant performance tests.

The BioFriend™ BioMask™ surgical facemasks are designed to fulfil the specifications of a high barrier class facemask as defined in the FDA recognised consensus standard, ASTM F2100-07 Standard Specification for Performance of Materials used in Medical Face Masks. The performance

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specifications are listed in Table 11.1. The test methodology used to assess the performance of the BioFriend™ BioMask™ is further described in Section 18.1, and full test reports are appended in Appendix 9 and 18.

Table 11.1 Summary of BioFriend™ BioMask™ Surgical Facemask Performance

Description	Test Method	ASTM F2100-07 High Barrier Class Performance Requirement	BioFriend™ BioMask™ Surgical Facemask

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11.3.2 Mask Styles

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[redacted]

11.3.2.1 Model: Universal BF-200-2001

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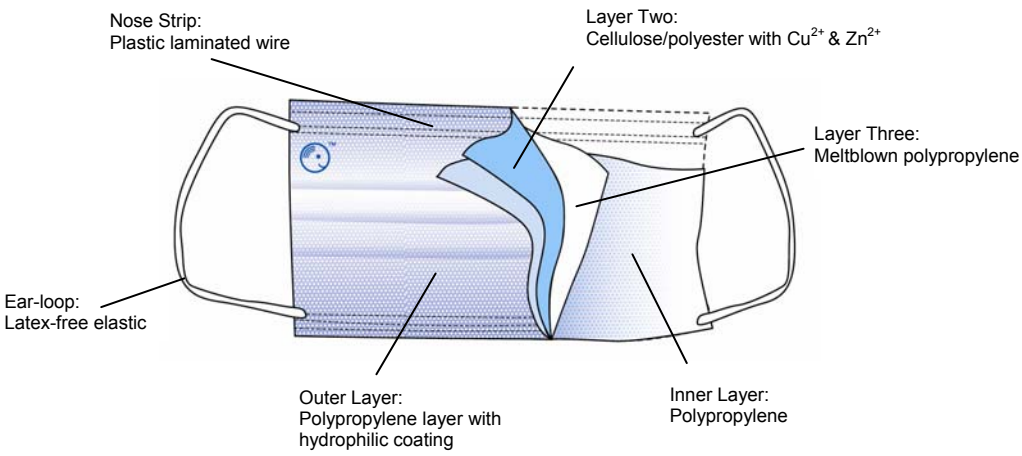
Figure 11.1 Model: Universal BF-200-2001



11.3.2.2 Model: Premium BF-200-3013

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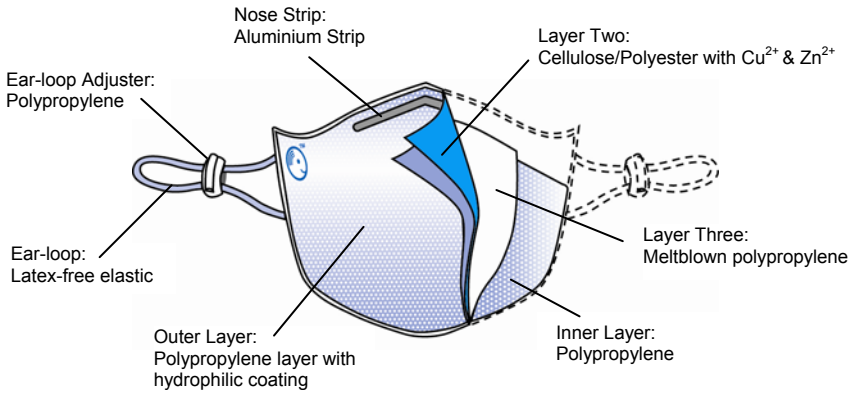
Figure 11.2 Model: Premium BF-200-3013



11.3.3 Material Composition

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. Both models are comprised of four layers of material: an outer layer of spun-bond

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along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard “comfort” features such ear adjusters and an anti-fog nose insert. The materials used in the composition of the BioFriend™ BioMask™ surgical facemask models are summarised in Table 11.2.

Table 11.2 Summary of BioFriend™ BioMask™ Surgical Facemask Material Composition

	BioFriend™ BioMask™ Surgical Facemask Model: Universal BF-200-2001	BioFriend™ BioMask™ Surgical Facemask Model: Premium BF-200-3013
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11.3.3.1 Spun-bond Polypropylene with Hydrophilic Coating

The outer spun-bond polypropylene layer (a standard mask construction material) has been coated

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11.3.3.1.1 Preparation of a Spun-bond Polypropylene Textile with a Hydrophilic Plastic Coating

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11.3.3.2 Cellulose/Polyester Textile Treated with Copper and Zinc

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11.3.3.2.1 Preparation of Cellulose/Polyester Textile Treated with Copper and Zinc

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11.3.3.3 Relative Contribution of Mask Textile Layers and Chemical Constituents

Polypropylene textile layers are typically used in the manufacture of facemasks as the heat-moldable layers permit the shaping of facial masks with heat or ultrasonic welding, and allow for high speed manufacturing. Polypropylene textiles by nature are hydrophobic; repel moisture, so that any aerosol

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droplets that contact the surface of the facemask remain on the surface, unless they are drawn through the polypropylene layer with inhalation. The outer layer polypropylene has been coated with a durable plastic coating that decreases the hydrophobicity of the polypropylene-based textile, and thereby increases the transmission of aerosol droplets into a juxtaposed and inner layer of the mask, where influenza viruses are inactivated by the divalent metal ions, copper and zinc and low pH.

To demonstrate effectiveness of the hydrophilic plastic coating to decrease the hydrophobicity of the polypropylene-based textile, facemasks were made with an outer layer of either uncoated polypropylene or polypropylene with the hydrophilic coating. These outer layers were combined with the other three layers of the mask, a second layer of cellulose/polyester (with the divalent metal ions copper and zinc), a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of

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[redacted]

live virus, which was then quantified by infectivity in a host cell line. Results of the test are summarized in Table 11.3, and are discussed further in Section 18.4.

Table 11.3 Relative Contribution of Mask Textile Layers and Chemical Constituents to Antiviral Efficacy

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[redacted]

The addition of the hydrophilic plastic coating to the outer layer polypropylene results in a substantial increase in virucidal activity of the facemask.

11.4 Characterization of Chemical Constituents

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. The BioFriend™ BioMask™ surgical facemask has an outer hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into a juxtaposed and inner layer of the

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mask where influenza viruses are inactivated through the action of divalent metal ions, copper and zinc, and low pH.

11.4.1 Mode of Action

The divalent metal ions copper and zinc are both cationic and surface active. They inactivate viruses

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Citric acid, used as the hydrophilic plasticizing agent for the polyvinyl coating, is an organic carboxylic

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11.4.2 Spectrum of Activity

11.4.2.1 Copper

The virucidal efficacy of copper against influenza viruses has been known for a long time (Table 11.5). In 1944, Dunham & MacNeal reported the inactivation of influenza A virus (Melbourne strain) by 1% copper. More recently, Nagayama (2006) reported that the minimum lethal concentration of $CuCl_2$ to reduce the infectivity of Influenza A H1N1 A/WSN/33 virus by 4 log in 1 hour was 0.025% (w/v). Horie *et al.* (2008) has reported that 25 uM $CuCl_2$ or $CuSO_4$ reduces the infectivity of avian influenza H9N2

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virus by nearly 3 and 4 log ($TCID_{50}$) within 3 and 6 hours, respectively. With 250 uM $CuCl_2$ or $CuSO_4$ the virus infectivity declined by 2 log in 1 hour. More dilute solutions (2.5 uM) were found less effective, but virus infectivity still decreased by >4.5 log in 12 hours. Experiments using the zinc salts $ZnCl_2$ or $ZnSO_4$, and the metal chelator EDTA suggested that the H9N2 virus was irreversibly inactivated by Cu^{2+} and not by the chloride ions, sulphate ions or acidic pH of the test solutions (of 5.5 to 5.6). Copper surfaces have also been demonstrated to inactivate influenza A virus. In a study where influenza A H1N1 A/PR/8/34 was inoculated on copper coupons an initial inoculum of 6.3 log particles was reduced to 5.7 log particles after 1 hour and to 2.7 logs after 6 hour, a decrease of nearly 4 log. In contrast 6 log particles were recovered from stainless steel coupons after 6 hours (Noyce *et al.,* 2007).

The virucidal efficacy of copper against other viruses has also been reported (Table 11.5). In one study copper ions were demonstrated to inactivate five enveloped or non-enveloped, single or double stranded DNA or RNA viruses: the bacteriophages ΦX174, T7 and Φ6; and Herpes Simplex Virus and Junin virus (Sagripanti *et al.* 1993). Copper ions have also been demonstrated to inactivate the enveloped viruses HIV-1 (Sagripanti & Lightfoote, 1996; Borkow *et al.,* 2008) and Herpes Simplex Virus (HSV) (Sagripanti *et al.,* 1997).

Table 11.4 Referenced Antiviral Spectrum of Copper

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Table 11.5 Assessment of the Virucidal Efficacy of Copper Acetate against Influenza A A/Brisbane/59/2007

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[redacted]

Table 11.6 Assessment of the Virucidal Efficacy of Copper Acetate against Influenza B/Brisbane/60/2008

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11.4.2.2 Zinc

The virucidal efficacy of zinc is also well reported (Table 11.5). Horie *et al.* (2008) found that 250 uM of $ZnCl_2$ or $ZnSO_4$ reduced the infectivity of avian influenza H9N2 by 1.5 log in 24 hours. Zinc salts have also been demonstrated to have virucidal activity against the enveloped RNA and DNA viruses, Vaccinia Virus (Katz *et al.,* 1981), Human Immunodeficiency Virus (HIV) (Haraguchi *et al.,* 1999), Herpes Simplex Virus (HSV) (Arens & Travis, 2000) and Respiratory Syncytial Virus (RSV) (Saura *et al.,* 2004)

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[redacted]

Table 11.7 Antiviral Spectrum of Zinc

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Table 11.7 Assessment of the Virucidal Efficacy of Zinc Acetate against Influenza A A/Brisbane/59/2007

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[redacted]

Table 11.8 Assessment of the Virucidal Efficacy of Zinc Acetate against Influenza B/Brisbane/60/2008

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11.5 Development of Antiviral Resistance

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Appendix 11

Contents

A	Arens, M., Travis, S. (2000). Zinc salts inactivate clinical isolates of herpes simplex virus in vitro. *J Clin Microbiol;* 38(5):1758-62	11-18
B	Dunham, W.B., Mac Neal, W.J. (1944) Inactivation of influenza virus by mild antiseptics. *J. Immunol.* 49:123-128	11-23
C	Haraguchi, Y., Sakurai, H., Hussain, S., Anner, B.M., Hoshino, H. (1999) Inhibition of HIV-1 infection by zinc group metal compounds. *Antiviral Res.* 43(2):123-33.	11-29
D	Horie, M., Ogawa, H., Yoshida, Y., Yamada, K., Hara, A., Ozawa, K., Matsuda, S., Mizota, C., Tani, M., Yamamoto, Y., Yamada, M., Nakamura, K., Imai, K. (2008) Inactivation and morphological changes of avian influenza virus by copper ions. *Arch Virol* 153:1467-1472	11-40
E	Katz, E. Margalith, E. (1981) Inhibiton of vaccinia maturation by zinc chloride. *Antimicrob. Agents Chemother.* 19(2): 213-217	11-46
F	Letelier, M.E., Lepe, A.M., Faúndez, M., Salazar, J., Marín, R., Aracena, P., Speisky, H. (2005) Possible mechanisms underlying copper-induced damage in biological membranes leading to cellular toxicity. *Chem. Biol. Interact.* 151(2):71-82	11-51
G	Noyce, J.O. Michels, H., Keevil, C.W. (2007) Inactivation of Influenza A virus on copper versus stainless steel surfaces. *Appl. Environ. Microbiol.* 73(8):2748-50	11-63
H	Rennie, P., Bowtell, P., Hull, D., Charbonneau, D., Lambkin-Williams, R., Oxford, J. (2008) Low pH gel intranasal sprays inactivate influenza viruses in vitro and protect ferrets against influenza infection. *Respiratory Res.* 8:38	11-66
I	Sagripanti, J.L. and Lightfoote, M.M. (1996) Cupric and ferric ions inactivate HIV. *AIDS Res. Hum. Retroviruses* 12:333-337	11-73
J	Sagripanti, J.L., Routson, L.B. and Lytle, C.D. (1993) Virus inactivation by copper or iron ions alone or in the presence or perioxide. *Appl. Environ. Microbiol.* 59:4374-4376	11-77
K	Sagripanti, J.L., Routson, L.B., Bonifacino, A.C. and Lytle, C.D. (1997) Mechanisms of copper-mediated inactivation of herpes simplex virus. *Antimicrob. Agents Chemother.* 41(4): 812-817	11-80
L	Stock, C., Francis, T. (1940) The inactivation of the virus of epidemic influenza by soaps. *J Exp Med.* 71(5):661–681	11-86
M	Suara, R.O, Crowe, J.E. (2004) Effect of zinc salts on respiratory syncytial virus replication. *Antimicrob Agents Chemother.* 48(3):783-90	11-107

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12 Substantial Equivalence Discussion

21 CFR 807.92 requires any new device to be “substantially equivalent” to a current legally marketed device from the same class. As indicated by the FDA/CDRH on October 10, 2008 in its 513g response letter to Filligent, the relevant class for both models of the BioFriend™ BioMask™ surgical facemask is a Class II Surgical Face Mask (see 513g letter appended to Section 21). The Class II Surgical Face Mask predicate chosen for the BioFriend™ BioMask™ surgical facemasks is the current and legally marketed Prestige Ameritech Facemask (K061716). A comparison of the predicate to both models of the BioFriend™ BioMask™ surgical facemask is set forth in Table 12.1 below.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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13 Proposed Labeling

The proposed labeling and marketing material to accompany the BioFriend™ BioMask™ Surgical Facemask is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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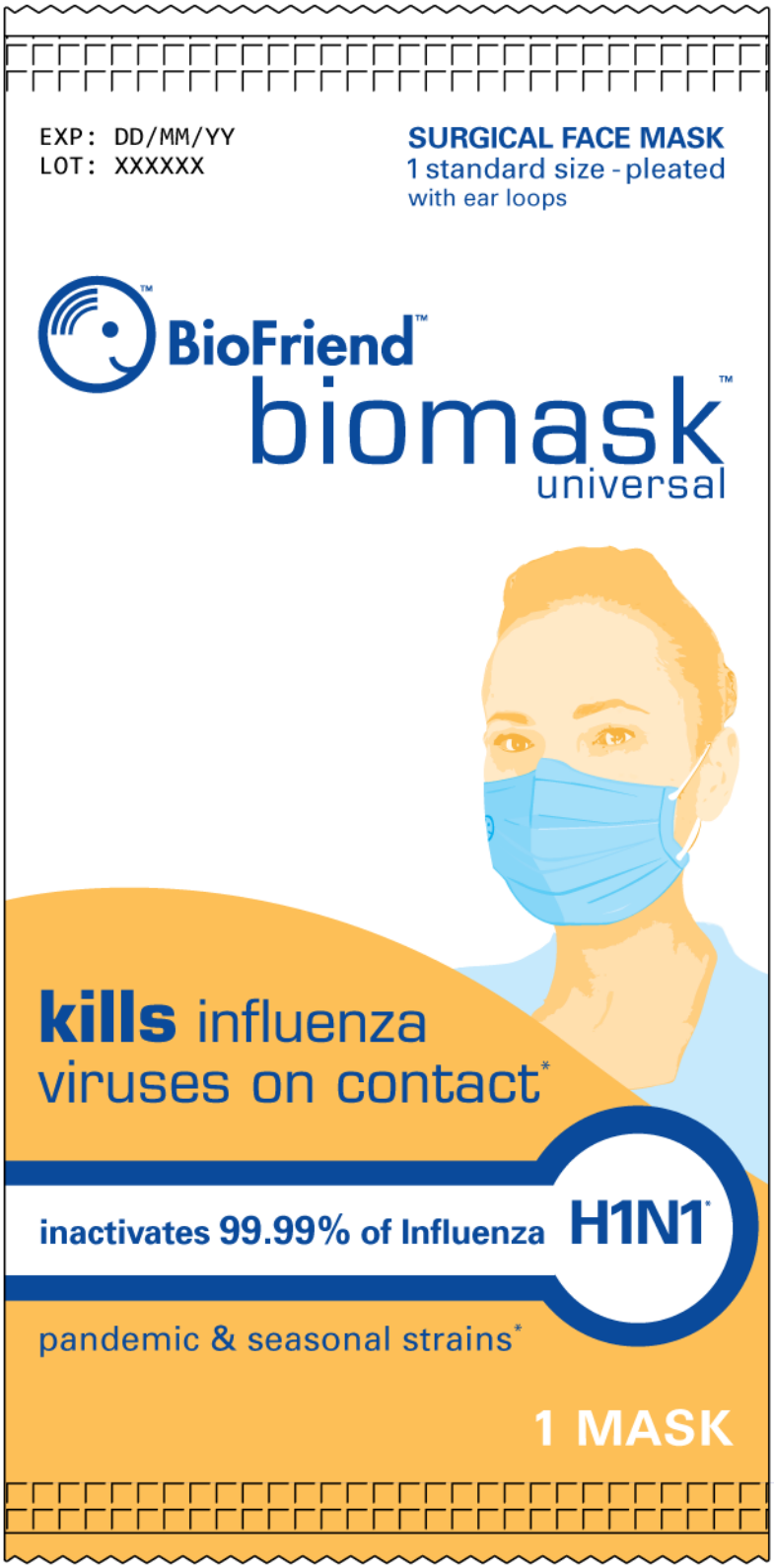
BioFriend™ BioMask™ Model: Universal BF-200-2001

Bag - Principal Display Panel - Front



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-2001

Bag - Reverse

BioFriend™ biomask™ universal

- Kills influenza viruses on contact*
- Inactivates Influenza A & B viruses*
- Pandemic & seasonal strains*
- Easy breathing
- Simple to use
- Comfortable face-design

High Barrier
Surgical Face Mask
Meets ASTM F2100-07 Standard

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated.

INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. It is also intended for use during periods of seasonal influenza or an influenza pandemic.

Meets ASTM F2100-07 High Barrier Class: Synthetic Blood Penetration Resistance - 160 mmHg; Flammability - Class 1; DP < 3.0; Bacterial Filtration Efficiency ≥ 98%; Particle Filtration Efficiency ≥ 98% at 0.1 micron.

Part of an innovative range of products powered by BioFriend™ technology.

Technology by:
filligent™
creating global health choices

Website: www.filligent-usa.com
Email: filligent-usa@filligent.com

DISPOSABLE SINGLE USE ONLY

inactivates 99.99% of **H1N1** influenza viruses*

*BioMask™ kills (inactivates) 99.99% of the following viruses within five minutes of contact with the surface of the facemask based on laboratory tests only.

Subtype	Isolate
INFLUENZA A	
H1N1	Pandemic H1N1, A/California/07/09 Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Swine (H1N1), A/Swine/1976/31
H2N2	Human (H2N2), A/2/JAPAN/305/57
H3N2	Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Hong Kong/8/68 Human (H3N2), A/Victoria/3/75
H3N8	Equine (H3N8), A/Equine/2/Miami/63
H5N1	Avian (H5N1), NIBRG-14
H5N2	Duck (H3N8), A/Duck/PA/10218/84
H9N2	Avian (H9N2), Turkey/Wis/66
INFLUENZA B	
B	Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40

WARNINGS / CONTRA-INDICATIONS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- This mask does not contain natural latex.
- For use in medical settings only.
- For adult use only.

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7th floor, 69 Jervois Street,
Sheung Wan, Hong Kong

REF BF-200-3013/P-1359

4 897026 663847

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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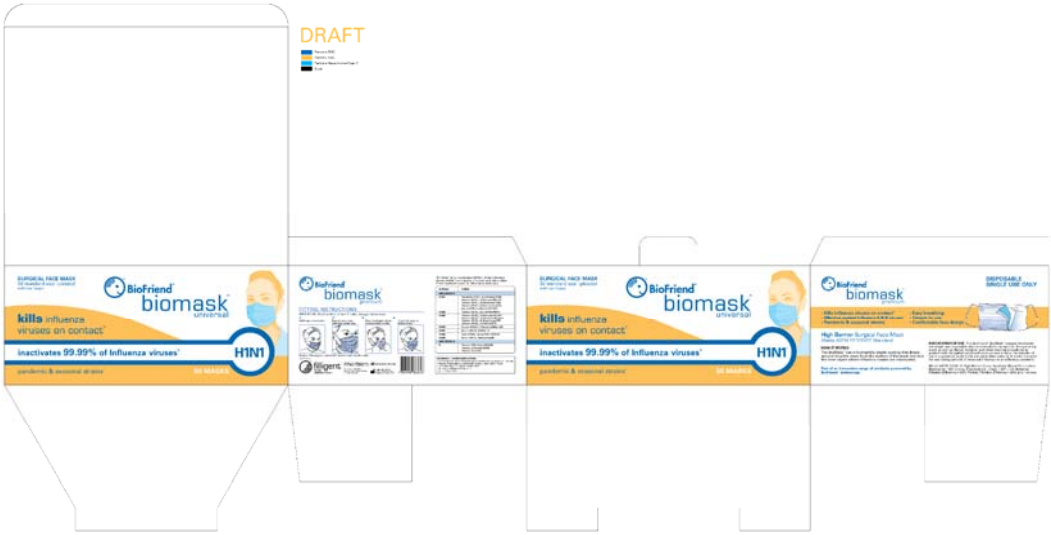
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

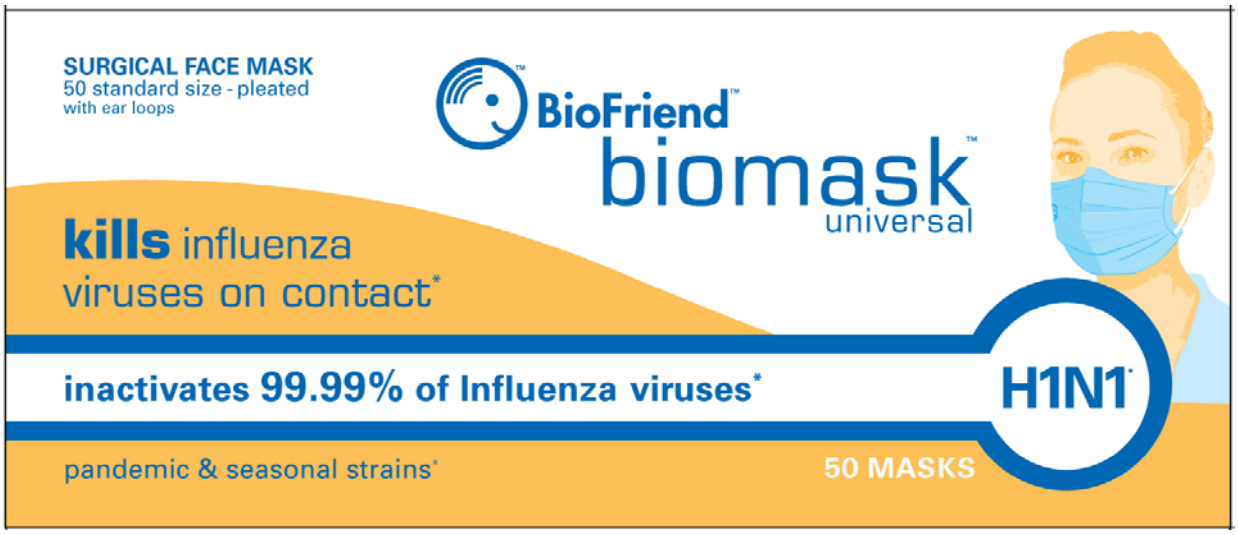
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-2001

Complete Box



Box - Principal Display Panel – Front & Reverse



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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box - Side Panel 1

BioFriend™
biomask™
premium

FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask

1 Pull loops around ears.

2 Expand mask over nose and under chin.

3 Press forefingers down on both sides of nose.

4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

Technology by:

filligent™ creating global health choices

Website: www.filligent-usa.com
Email: filligent-usa@filligent.com

REF BF-200-2001/P-1359/B-1206

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Filligent (HK) Limited
7th floor, 69 Jervois Street,
Sheung Wan, Hong Kong

4 897026 663878

*BioMask™ kills (inactivates) 99.99% of the following viruses within five minutes of contact with the surface of the facemask based on laboratory tests only.

Subtype	Isolate
INFLUENZA A	
H1N1	Pandemic H1N1, A/California/07/09 Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Swine (H1N1), A/Swine/1976/31
H2N2	Human (H2N2), A/2/JAPAN/305/57
H3N2	Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Hong Kong/8/68 Human (H3N2), A/Victoria/3/75
H3N8	Equine (H3N8), A/Equine/2/Miami/63
H5N1	Avian (H5N1), NIBRG-14
H5N2	Duck (H3N8), A/Duck/PA/10218/84
H9N2	Avian (H9N2), Turkey/Wis/66
INFLUENZA B	
B	Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40

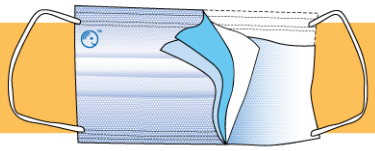
WARNINGS / CONTRA-INDICATIONS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- This mask does not contain natural latex.
- For use in medical settings only.
- For adult use only.

Box - Side Panel 2

BioFriend™
biomask™
premium

DISPOSABLE SINGLE USE ONLY

- **Kills influenza viruses on contact***
- **Effective against Influenza A & B viruses***
- **Pandemic & seasonal strains***
- **Easy breathing**
- **Simple to use**
- **Comfortable face-design**



High Barrier Surgical Face Mask
Meets ASTM F2100-07 Standard

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated.

Part of an innovative range of products powered by BioFriend™ technology.

INDICATIONS FOR USE: The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. It is also intended for use during periods of seasonal influenza or an influenza pandemic.

Meets ASTM F2100-07 High Barrier Class: Synthetic Blood Penetration Resistance - 160 mmHg; Flammability - Class 1; DP < 3.0; Bacterial Filtration Efficiency ≥ 98%; Particle Filtration Efficiency ≥ 98% at 0.1 micron.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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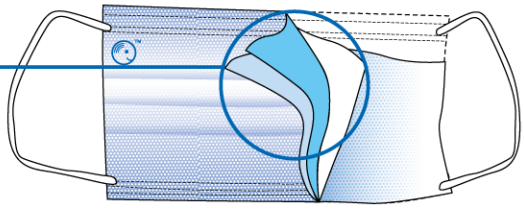
BioFriend™ BioMask™ Model: Universal BF-200-2001

Promotional Flyer

BioFriend™ biomask™ universal

SURGICAL FACE MASK PLEATED

Triple protection



1. **FILTERS:** High Barrier Medical Face Mask (ASTM F2100-07)
2. **KILLS:** Inactivates 99.99% of Influenza viruses*
3. **BREATHES:** Optimizes comfortable breathing

- **Kills influenza viruses on contact***
- **Inactivates Influenza A & B viruses***
- **Pandemic & seasonal strains***
- **Easy breathing**
- **Simple to use**
- **Comfortable face-design**

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated.

INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. It is also intended for use during periods of seasonal influenza or an influenza pandemic.

Meets ASTM F2100-07 High Barrier Class: Synthetic Blood Penetration Resistance - 160 mmHg; Flammability - Class 1; DP < 3.0; Bacterial Filtration Efficiency ≥ 98%; Particle Filtration Efficiency ≥ 98% at 0.1 micron.

*BioMask™ kills (inactivates) 99.99% of the following viruses within five minutes of contact with the surface of the facemask based on laboratory tests only.

Subtype	Isolate
Influenza A	
H1N1	Pandemic H1N1, A/California/07/09 Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Swine (H1N1), A/Swine/1976/31
H2N2	Human (H2N2), A/2/Japan/305/57
H3N2	Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Hong Kong/8/68 Human (H3N2), A/Victoria/3/75
H3N8	Equine (H3N8), A/Equine/2/Miami/63
H5N1	Avian (H5N1), NIBRG-14
H5N2	Duck (H3N8), A/Duck/PA/10218/84
H9N2	Avian (H9N2), Turkey/Wis/66
Influenza B	
B	Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40

Part of an innovative range of products powered by BioFriend™ technology.

kills influenza viruses on contact*

inactivates 99.99% of Influenza viruses* **H1N1***

pandemic & seasonal strains*

Technology by: filligent™ creating global health choices

Pragmatic • Scientific • Patented

Website: www.filligent-usa.com
Email: filligent-usa@filligent.com

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WARNINGS / CONTRA-INDICATIONS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- This mask does not contain natural latex.
- For use in medical settings only.
- For adult use only.

Rev 1 20/04/2010

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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BioFriend™ BioMask™ Model: Premium BF-200-3013

Bag - Principal Display Panel - Front

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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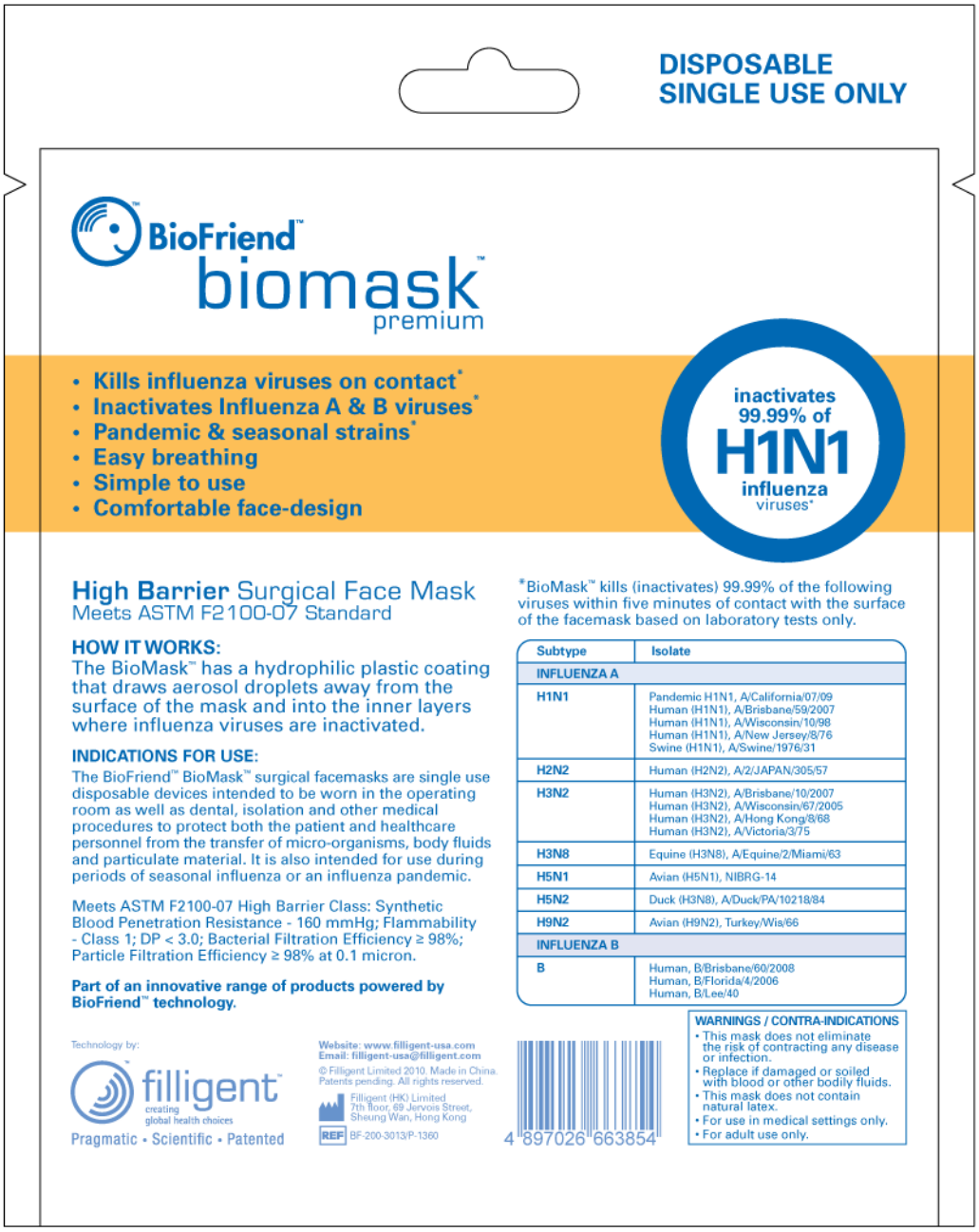
BioFriend™ BioMask™ Model: Premium BF-200-3013

Bag - Reverse



DISPOSABLE
SINGLE USE ONLY

BioFriend™
biomask™
premium

- Kills influenza viruses on contact*
- Inactivates Influenza A & B viruses*
- Pandemic & seasonal strains*
- Easy breathing
- Simple to use
- Comfortable face-design

inactivates 99.99% of H1N1 influenza viruses*

High Barrier Surgical Face Mask
Meets ASTM F2100-07 Standard

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated.

INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. It is also intended for use during periods of seasonal influenza or an influenza pandemic.

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Part of an innovative range of products powered by BioFriend™ technology.

*BioMask™ kills (inactivates) 99.99% of the following viruses within five minutes of contact with the surface of the facemask based on laboratory tests only.

Subtype	Isolate
INFLUENZA A	
H1N1	Pandemic H1N1, A/California/07/09 Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Swine (H1N1), A/Swine/1976/31
H2N2	Human (H2N2), A/2/JAPAN/305/57
H3N2	Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Hong Kong/8/68 Human (H3N2), A/Victoria/3/75
H3N8	Equine (H3N8), A/Equine/2/Miami/63
H5N1	Avian (H5N1), NIBRG-14
H5N2	Duck (H3N8), A/Duck/PA/10218/84
H9N2	Avian (H9N2), Turkey/Wis/66
INFLUENZA B	
B	Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40

WARNINGS / CONTRA-INDICATIONS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- This mask does not contain natural latex.
- For use in medical settings only.
- For adult use only.

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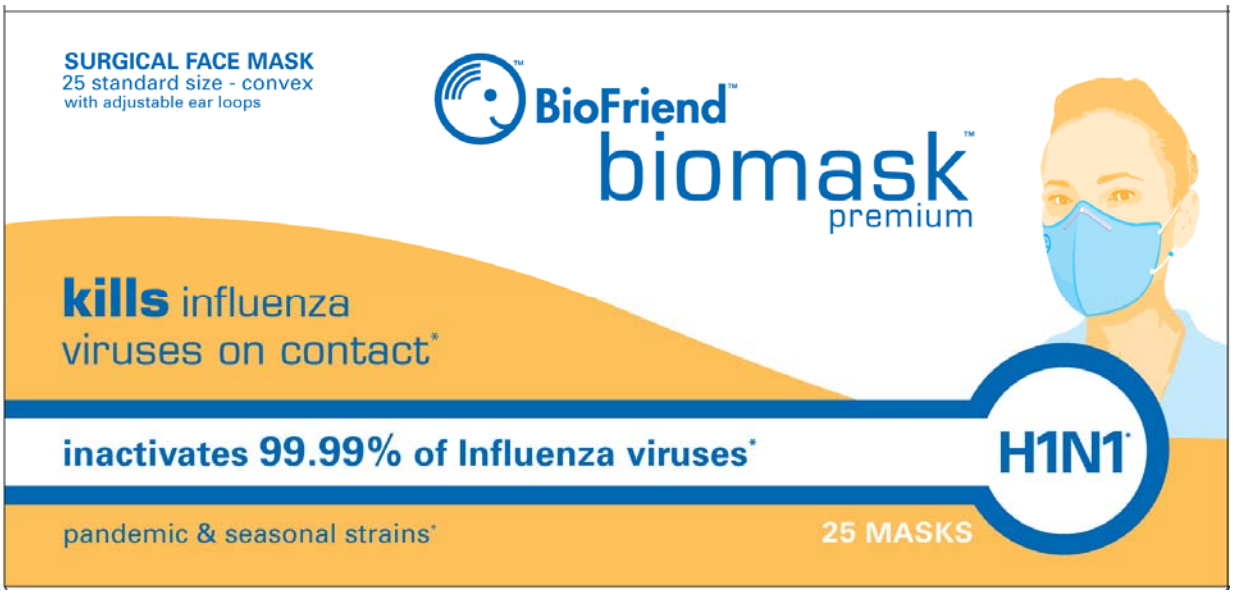
BioFriend™ BioMask™ Model: Premium BF-200-3013

Complete Box

Box – Principal Display Panel - Front & Back



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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Premium BF-200-3013

Box – Side Panel 1

BioFriend™ biomask™ premium

DISPOSABLE SINGLE USE ONLY

FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask

1. Cup mask over nose and under chin.
2. Put loop around ears. Adjust as required.
3. Press forefingers down on both sides of nose.
4. Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

*BioMask™ kills (inactivates) 99.99% of the following viruses within five minutes of contact with the surface of the facemask based on laboratory tests only.

Subtype	Isolate
INFLUENZA A	
H1N1	Pandemic H1N1, A/California/07/09 Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Swine (H1N1), A/Swine/1976/31
H2N2	Human (H2N2), A/2/JAPAN/305/57
H3N2	Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Hong Kong/8/68 Human (H3N2), A/Victoria/3/75
H3N8	Equine (H3N8), A/Equine/2/Miami/63
H5N1	Avian (H5N1), NIBRG-14
H5N2	Duck (H3N8), A/Duck/PA/10218/84
H9N2	Avian (H9N2), Turkey/Wis/66
INFLUENZA B	
B	Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40

WARNINGS / CONTRA-INDICATIONS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- This mask does not contain natural latex.
- For use in medical settings only.
- For adult use only.

Technology by: filligent™ creating global health choices

Website: www.filligent-usa.com
Email: filligent-usa@filligent.com

REF BF-200-3013/P-1360/B-1207

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Filligent (HK) Limited
7th floor, 69 Jervois Street,
Sheung Wan, Hong Kong

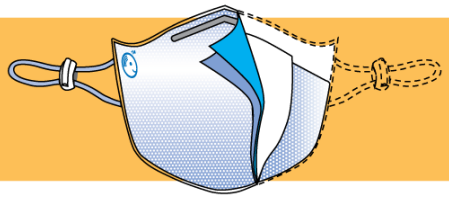
4 897026 663861

Box – Side Panel 2

BioFriend™ biomask™ premium

DISPOSABLE SINGLE USE ONLY

- **Kills influenza viruses on contact***
- **Effective against Influenza A & B viruses***
- **Pandemic & seasonal strains***
- **Easy breathing**
- **Simple to use**
- **Comfortable face-design**



High Barrier Surgical Face Mask
Meets ASTM F2100-07 Standard

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated.

Part of an innovative range of products powered by BioFriend™ technology.

INDICATIONS FOR USE: The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. It is also intended for use during periods of seasonal influenza or an influenza pandemic.

Meets ASTM F2100-07 High Barrier Class: Synthetic Blood Penetration Resistance - 160 mmHg; Flammability - Class 1; DP < 3.0; Bacterial Filtration Efficiency ≥ 98%; Particle Filtration Efficiency ≥ 98% at 0.1 micron.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

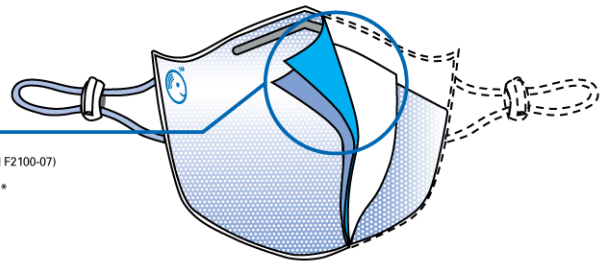
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Premium BF-200-3013

Promotional Flyer

BioFriend™ biomask™ premium

SURGICAL FACE MASK CONVEX



Triple protection

1. **FILTERS:** High Barrier Medical Face Mask (ASTM F2100-07)
2. **KILLS:** Inactivates 99.99% of Influenza viruses*
3. **BREATHES:** Optimizes comfortable breathing

- **Kills influenza viruses on contact***
- **Inactivates Influenza A & B viruses***
- **Pandemic & seasonal strains***
- **Easy breathing**
- **Simple to use**
- **Comfortable face-design**

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated.

INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. It is also intended for use during periods of seasonal influenza or an influenza pandemic.

Meets ASTM F2100-07 High Barrier Class: Synthetic Blood Penetration Resistance - 160 mmHg; Flammability - Class 1; DP < 3.0; Bacterial Filtration Efficiency ≥ 98%; Particle Filtration Efficiency ≥ 98% at 0.1 micron.

*BioMask™ kills (inactivates) 99.99% of the following viruses within five minutes of contact with the surface of the facemask based on laboratory tests only.

Subtype	Isolate
Influenza A	
H1N1	Pandemic H1N1, A/California/07/09 Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Swine (H1N1), A/Swine/1976/31
H2N2	Human (H2N2), A/2/Japan/305/57
H3N2	Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Hong Kong/8/68 Human (H3N2), A/Victoria/3/75
H3N8	Equine (H3N8), A/Equine/2/Miami/63
H5N1	Avian (H5N1), NIBRG-14
H5N2	Duck (H3N8), A/Duck/PA/10218/84
H9N2	Avian (H9N2), Turkey/Wis/66
Influenza B	
B	Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40

Part of an innovative range of products powered by BioFriend™ technology.

kills influenza viruses on contact*

inactivates 99.99% of Influenza viruses* **H1N1***

pandemic & seasonal strains*

Technology by: filligent™ creating global health choices

Pragmatic • Scientific • Patented

Website: www.filligent-usa.com
Email: filligent-usa@filligent.com

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WARNINGS / CONTRA-INDICATIONS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- This mask does not contain natural latex.
- For use in medical settings only.
- For adult use only.

Rev 1 20/04/2010

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

14 Sterilization and Shelf Life

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only. The physical characteristics and materials used in the construction of the BioFriend™ BioMask™ surgical facemasks are equivalent to those of the predicate devices, the Prestige Ameritech Face Mask (K061716). No significant change in the performance of the facemask as a barrier is expected during the indicated shelf-life period. In addition to its barrier function, the BioFriend™ BioMask™ surgical facemask incorporates chemical constituents which impart virucidal activity to the facemask, with the facemask claimed to inactivate (kill) 99.99% of influenza viruses within 5 minutes contact with the surface of the mask, under tested conditions. Performance of the BioFriend™ BioMask™ surgical facemask against influenza will be evaluated during real-time and accelerated aging of the device following a defined written procedure for establishing and monitoring shelf-life, appended to Section 14. The BioFriend™ BioMask™ surgical facemasks are to be labelled with a shelf-life that is supported by testing. An outline of procedures implemented for monitoring the maintenance of antiviral efficacy of the BioFriend™ BioMask™ surgical facemask against influenza with ageing is discussed in Section 14.1.

14.1 Evaluation of the Virucidal Efficacy of the BioFriend™ BioMask™ Surgical Facemask with Ageing

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Appendix 14

Contents

A Shelf Life Assessment Procedure for BioFriend BioMask, Model Numbers BF-200-2001 and BF-200-3013. 14-4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Appendix A

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creating global health choices

STRICTLY CONFIDENTIAL
NOT FOR DISTRIBUTION

Shelf-Life Assessment Procedure

For

BioFriend™ BioMask™

(b)(4) Shelf-Life Assessment Procedure

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Shelf-Life Assessment Procedure

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(b)(4) Shelf-Life Assessment Procedure

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15 Biocompatability

Contents

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical face masks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second layer is treated with copper and zinc. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip. One model is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard “comfort” features such ear adjusters and an anti-fog nose insert.

Studies were performed to determine the safety of the BioFriend™ BioMask™ surgical facemask on contact with the body. Tests were conducted to evaluate the dermal irritation potential (Section 15.1) (b)(4) [redacted]

Release of the chemical constituents from the BioFriend™ BioMask™ surgical facemask due to (b)(4) [redacted] BioFriend™ BioMask™ surgical facemask.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

15.1 Irritation

The primary skin irritation test was used to determine the dermal irritation potential of the BioFriend™ BioMask™ surgical facemask materials on the shaved skin of rabbits. The test is covered in *ISO 10993-Part 10: Tests for Irritation – In Vivo*.

15.1.1 Outline of Methodology

(b)(4)

[redacted]

15.1.2 Results and Discussion

(b)(4)

[redacted]

15.1.3 Test Report

Full test report is appended in appendix 15.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

15.2 Sensitization

The Repeated Patch Dermal Sensitization Test - Buehler Method was used to evaluate the allergenic potential or sensitizing capacity of the BioFriend™ BioMask™ surgical facemask materials. This test procedure screens for contact allergens in guinea pigs with results extrapolated to humans. The test is covered in *ISO 10993-Part 10: Tests for Irritation – In Vivo*.

15.2.1 Outline of Methodology

(b)(4)

[redacted]

15.2.2 Results and Discussion

(b)(4)

[redacted]

15.2.3 Test Report

Full test report is appended in Appendix 15.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

15.3 Analysis of Extractables under Dynamic Flow Conditions Simulating Inhalation

The objective of this study was to characterize the chemical components which are released from the BioFriend™ BioMask™ surgical facemask when subjected to constant flow of humidified air simulating

(b)(4)

[redacted]

Characterisation of Materials and are intended to provide chemical characterization of components extracted from the BioFriend™ BioMask™ surgical facemask.

15.3.1 Outline of Methodology

(b)(4)

[redacted]

samples were used to demonstrate method accuracy and sensitivity. See Figure 15.1 for a schematic of the experimental set up used for determining the extractables from surgical masks under dynamic flow conditions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Figure 15.1 Experimental Design

(b)(4)

[redacted]

Table 15.2 Summary of Test Parameters

Test Materials	BioFriend™ BioMask™ surgical facemask Model: Premium BF-200-3013, Lot # 2010/02/06

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

15.3.2 Results and Discussion

It is believed that the test conditions are far more aggressive than actual use conditions. Under the test

(b)(4)

[redacted]

relevant detection limits are summarized in Table 15.3.

Table 15.3 Summary of Air Concentrations (mg/m^3) of Target Metals and Organics Released by Masks into the Air Stream at the First Sampling Time Point

(b)(4)

[redacted]

These results were subsequent used by an independent toxicologist to make a toxicological assessment of the released chemical constituents in BioFriend™ BioMask™ surgical facemask, Section 15.5.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

15.3.3 Test Report

Full test report is appended in Appendix 15.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

15.4 Analysis of Extractables under Polar and Non-Polar Solvent Exposure Conditions Simulating Salivary Contact

The objective of this study was to characterize the chemical constituents that are leached from the

(b)(4)

[redacted]

15.4.1 Outline of Methodology

A known amount of the BioFriend™ BioMask™ surgical facemask (Model: Premium BF-200-3013)

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

extractables from the BioFriend™ BioMask™ surgical facemask on exposure to 0.9% saline and hexane.

Figure 15.2 Experimental Design

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Table 15.4 Summary Of Test Parameters

(b)(4)

[redacted]

15.4.2 Results and Discussion

(b)(4)

[redacted]

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

These results were subsequently used by an independent toxicologist to make a toxicological assessment of the released chemical constituents in BioFriend™ BioMask™ surgical facemask - Section 15.5.

15.4.3 Report

Full test report is appended in Appendix 15.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

15.5 Toxicological Assessment of the Released Chemical Constituents in BioFriend™ BioMask™

Test data on the release of chemical constituents from the BioFriend™ BioMask™ surgical facemask under humidified dynamic flow condition simulating inhalation (Section 15.3) and on exposure to polar (0.9% saline) and non-polar solvents (hexane) simulating release on salivary contact (Section 15.4) were used by an independent toxicologist to conduct a toxicological assessment for an 8 hour adult exposure to the extractables (report appended in Appendix 15). The 8 hour exposure was used for the assessment, as this was the sampling point in the solvent extractable study for which the highest values were generally reported. Tables 15.6 to 15.10 summarise the information used by the toxicologist during the assessment.

Table 15.6 Amount of Chemical Constituents in the Mask

(b)(4)

[redacted]

Table 15.7 Information Pertinent to the Personal Exposure and Toxicity Assessment

Factor	Measurement

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

* volume of air breathed by a 70kg adult during an 8 hr period

15.5.1 Toxicity Assessment for an 8 Hour Adult Exposure to BioFriend™ BioMask™ Surgical Facemask Leachables

(b)(4)

[redacted]

Table 15.11 Determination of Maximum Extractable Exposure for 8 an Hour Adult Exposure

Extractable Chemical Exposure	Reported Toxicity Level*	Test Data from Characterization Tests	Estimated Maximum Exposure per 8 hr day

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

15.5.2 Toxicity Assessment Summary/Conclusion

The levels of the chemicals constituents in the polar and non-polar extracts from the BioFriend™ BioMask™ surgical facemask are at a low level. This along with the references to reported toxicity levels, and the biocompatibility test results support that no adverse health effects would be expected from the chemical constituents. Furthermore, the level of human exposure was based upon the entire face contact of the mask which would exceed the amount of the mask in contact with the nose and mouth, and using simulated extraction conditions which are not expected during normal use of the facemask.

During normal use no toxicity risk from the chemical constituents or chemical extractables from the BioFriend™ BioMask™ surgical facemasks is expected. The amounts of leachable chemicals are below levels of toxicity concern. This assessment supports the safe use of the BioFriend™ BioMask™ surgical facemasks.

15.5.3 Report

Toxicity Risk Assessment of the Chemical Extractables from the BioFriend™ BioMask™, BF-200-3013, Lot # 2010/02/06, Wuxi AppTec Inc. 2540 Executive Drive, St Paul, MN 55120, 8 April 2010

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Appendix 15

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

16 Software

This section does not apply. The device incorporates no software.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

17 Electromagnetic Compatibility and Electrical Safety

This section does not apply. The device is not an electronic device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

18 Performance Testing – Bench

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical face masks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second layer is treated with copper and zinc. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip. One model is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard “comfort” features such ear adjusters and an anti-fog nose insert.

(b) (4)

[redacted]

Virudical suspension assay tests using human influenza A/Brisbane/59/2007 and B/Brisbane/60/2008 were conducted in accordance with *E 1052-96 Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension* to support the *in vitro* activity of copper and zinc against influenza virus. A summary of the test methodology and results is presented Section 18.3.

The outer spun-bond polypropylene layer of the BioFriend™ BioMask™ surgical facemask has been coated with a durable plastic coating that decreases the hydrophobicity of the polypropylene-based textile, and thereby increases the transmission of aerosol droplets into the inner layers of the mask, where influenza viruses are inactivated by the divalent metal ions, copper and zinc and low pH. The effectiveness of the hydrophilic coating to decrease the hydrophobicity of the polypropylene-based textile was assessed using facemasks made with an outer layer of either uncoated polypropylene or polypropylene with the hydrophilic coating. Each facemask type was then tested for virucidal efficacy. A summary of the test methodology and results is presented in Section 18.5.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

18.1 Evaluation of the Performance of the BioFriend™ BioMask™ Surgical Facemask

The materials of construction used in the BioFriend™ BioMask™ surgical facemask conform to the performance requirements for materials used in facemasks set out in the recognised FDA consensus standard: *ASTM F2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks* (Table 18.1). Performance testing assessed bacterial filtration efficiency, differential pressure, sub-micron particulate filtration efficiency, resistance to penetration by synthetic blood, and flammability.

Table 18.1: Medical Face Mask Material Requirements By Performance Class – ASTM F2100-07

Characteristic	Low Barrier	Moderate Barrier	High Barrier
(b)(4) [redacted]			

18.1.1 Outline of Methodology

Performance of the materials of construction used in the BioFriend™ BioMask™ surgical facemask was assessed using the standard test methodologies referenced in the FDA recognised consensus standard *ASTM F2100-07 Standard Specification of Performance of Materials Used in Medical Face Masks*:

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

18.1.1.1 Bacterial Filtration Efficiency

(b)(4)

[redacted]

18.1.1.2 Sub-micron (0.1 µm) Particulate Filtration Efficiency

(b)(4)

[redacted]

18.1.1.3 Breathing Resistance

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

18.1.1.4 Fluid Resistance

(b)(4)

[redacted]

18.1.1.5 Flammability

(b)(4)

[redacted]

18.1.2 Results and Discussion

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Barrier performance class

18.1.3 Test Reports

Full test reports are appended in Appendix 18.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

18.2 Antimicrobial Effectiveness Testing - Evaluation of Virucidal Efficacy of the BioFriend™ BioMask™ Surgical Facemask.

In vitro laboratory testing was used to demonstrate the efficacy of the BioFriend™ BioMask™ surgical facemask against influenza using 18 influenza subtypes including; the circulating H1N1; recent vaccine isolates; major re-assortments; and avian and animal (equine and swine) isolates; that encompasses many of the influenza subunits in circulation (Table 18.8). The study was conducted at Microbiotest Inc (USA) in compliance with the Good Laboratory Practice regulations. Laboratory tests were conducted in accordance with the suggestions provided by the FDA/CDRH detailed in the Pre-IDE meeting on July 30, 2009.

Table 18.7 List of Influenza Viruses Evaluated

Subtype	Isolate
Influenza A	
H1N1	Pandemic H1N1 Influenza Virus,A/California/07/09
	Human Influenza A Virus (H1N1), A/Brisbane/59/2007
	Human Influenza A Virus (H1N1), A/Wisconsin/10/98
	Human Influenza A Virus (H1N1), A/New Jersey/8/76
	Human Influenza A Virus (H1N1), A/PR/8/38
	Swine Influenza Virus (H1N1), A/Swine/1976/31
H2N2	Human Influenza A2 Virus (H2N2), A/2/JAPAN/305/57
H3N2	Human Influenza A Virus (H3N2), A/Brisbane/10/2007
	Human Influenza A Virus (H3N2), A/Wisconsin/67/2005
	Human Influenza A Virus (H3N2), A/Hong Kong/8/68
	Human Influenza A Virus (H3N2), A/Victoria/3/75
H3N8	Equine Influenza Virus (H3N8), A/Equine/2/Miami/63
H5N1	Avian Influenza Virus (H5N1), NIBRG-14
H5N2	Duck Influenza Virus (H3N8), A/Duck/PA/10218/84
H9N2	Avian Influenza Virus (H9N2), Turkey/Wis/66
Influenza B	
B	Human Influenza B Virus, B/Brisbane/60/2008
	Human Influenza B Virus, B/Florida/4/2006
	Human Influenza B Virus, B/Lee/40

18.2.1 Outline of Methodology

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

performed using the same level of viral challenge to serve as a control for the input virus load. The test

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[redacted]

The test was acceptable for evaluation if the following criterion was met:

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Figure 18.1 Experimental Design

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Table 18.8 Summary Of Test Parameters

Test Material:	BioFriend™ BioMask™ Surgical Facemask Model: BF-200-3013, Lot # 2010/02/06

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

18.2.2 Results and Discussion

Table 18.9 Viral Reduction of the BioFriend™ BioMask™ Surgical Facemask on 5 Minutes Surface Contact based on Control Mask

(b)(4)

[redacted]

***** No virus was detected; the theoretical titer was determined based on the Poisson distribution.
Results presented average of three replicates

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

influenza viruses.

18.2.3 Test Reports

Full test reports are appended in Appendix 18.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

18.3 Assessment of the Virucidal Effectiveness of the Metal Ions Copper and Zinc against Influenza

(b)(4)

[redacted]

18.3.1 Outline of Methodology

The virucidal efficacy of copper or zinc was evaluated against the challenge viruses in suspension.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Figure 18.2 Experimental Design

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Table 18.10 Summary of Test Parameters

(b)(4)

[redacted]

18.3.2 Results and Discussion

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Table 18.12 Assessment of the Virucidal Efficacy of Copper Acetate against Influenza B/Brisbane/60/2008

(b)(4)

[redacted]

Table 18.13 Assessment of the Virucidal Efficacy of Zinc Acetate against Influenza A/Brisbane/59/2007

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Table 18.14 Assessment of the Virucidal Efficacy of Zinc Acetate against Influenza B/Brisbane/60/2008

(b)(4)

[redacted]

18.3.3 Test Reports

Full test reports are appended in Appendix 18.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

18.4 Relative Contribution of Mask Textile Layers to the Virucidal Efficacy of the BioFriend™ BioMask™ Surgical Facemask.

Polypropylene textile layers are typically used in the manufacture of facemasks as the heat-moldable layers permit the shaping of facial masks with heat or ultrasonic welding, and allow for high speed manufacturing. Polypropylene textile by nature are hydrophobic; repel moisture, so that any aerosol droplets that contact the surface of the facemask remain on the surface, unless they are drawn through the polypropylene layer with inhalation. The outer layer polypropylene has been coated with a durable composition that decreases the hydrophobicity of the polypropylene-based textile, and thereby increases the transmission of aerosol droplets into the inner layers of the mask, where influenza viruses are inactivated by the divalent metal ions, copper and zinc and low pH. To demonstrate effectiveness of the hydrophilic coating to decrease the hydrophobicity of the polypropylene-based textile, facemasks were made with an outer layer of either uncoated polypropylene or polypropylene with the hydrophilic coating. These outer layers were combined with (the other three layers of the mask), a second layer of cellulose/polyester (with the divalent metal ions copper and zinc), a third layer of melt-blown polypropylene and an inner (fourth) layer of spun-bound polypropylene. Each facemask type was then tested for virucidal efficacy by misting live influenza A (H1N1) A/PR/8/38 onto the outer surface of samples cut from the facemask. The study was conducted at Microbiotest Inc, Sterling, Virginia (USA) in compliance with the Good Laboratory Practice regulations.

18.4.1 Outline of Methodology

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Figure 18.3 Experimental Design

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Table 18.15 Summary Of Test Parameters

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

18.4.2 Results and Discussion

Table 18.6 Relative Contribution of Mask Textile Layers and Chemical Constituents to Antiviral Efficacy

(b)(4)

[redacted]

Polypropylene textile by nature are hydrophobic; repel moisture, so that any aerosol droplets that

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[redacted]

hydrophilic coating of the polypropylene results in a substantial increase in virucidal efficacy of the facemask.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

18.4.3 Test Report

Test report is appended in Appendix 11

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Appendix 18

Content

(b)(4) Reports

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

19 Performance Testing – Animal

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

20 Performance Testing – Clinical

This section does not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0291, Exp.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Filligent (HK) Limited

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Apr 20, 2010

3. ADDRESS *(Number, Street, State, and ZIP Code)*
7th Floor, 69 Jervois Street, Sheung Wan, Hong Kong

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 852 2542 2400
(Fax) 852 2542 2411

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

BioFriend BioMask Surgical Facemask,
Models: Universal BF-200-2001 & Premium BF-200-3013

Classification Name: Mask, Surgical
Classification Regulation: 21 CFR 878.4040,

Product Code: FXX
Class II Medical Device,

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Melissa Mowbray-d'Arbela
(Title) Chief Executive Oficer

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
7th Floor, 69 Jervois Street, Sheung Wan, Hong Kong

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 852 2542 2400
(Fax) 852 2542 2411

15. DATE OF CERTIFICATION
Apr 20, 2010

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

21 Other

Discussion of Information/Recommendations made by FDA – pre IDE I090448

A pre-IDE teleconference was held between FDA, Filligent (HK) Limited, (Hong Kong, China) and Emergo Group, Inc. on July 30, 2009. This meeting was to provide feedback regarding the information provided in the Pre-IDE submission I090448 that was received by FDA on June 17, 2009.

The information/recommendations made by the FDA during the meeting are discussed below in relation to this 510(k) submission. The full meeting minutes are appended in Section 21, Appendix A.

Performance testing for Filligent (HK Limited, FM-200/Bio-Friend™ BioMask™ (the "BioMask"):

1. *FDA/CDRH does not approve antimicrobial drugs. CDER has not approved copper as an antimicrobial drug. Therefore, a 510(k) submission should include the level of in vitro antimicrobial performance testing which CDER would expect to receive to support an NDA prior to animal or human studies.*

Section 11.4.2 and 18.3 addresses the virucidal efficacy of copper against influenza. This has been

(b) (4) [redacted]

against influenza virus (Section 18.3).

2. *The firm stated they would like to narrow the antimicrobial performance claims to Influenza type A. The FDA informed the firm that the FDA needs good in vitro performance data against a wide range of strains of Influenza A. FDA suggested at least 18-20 strains of the virus be tested which should include both human and animal (avian, swine) strains. Testing should be performed on the final, finished, entire mask, not just one layer of the mask.*

Section 18.2 addresses this matter. In summary, in accordance with FDA suggestions the virucidal efficacy of the entire BioFriend™ BioMask™ surgical facemask against influenza was demonstrated in

(b)(4) [redacted]

Jersey/8/76, A/PR/8/38), H2N2 (A/2/JAPAN/305/57), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75); including the bird flu subtypes: H5N1 (NIBRG-14), H5N2 (A/Duck/PA/10218/84), H9N2 (Turkey/Wis/66); and the equine and swine subtypes: H1N1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(A/Swine/1976/31), H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Brisbane/60/2008,

(b)(4) [redacted]

18.2, and test reports are appended in Appendix 18.

3. *FDA stated that some of the results in the firm's I090448, show a great deal of variation in results and significant nonspecific antimicrobial activity in the negative control specimens. FDA suggested negative controls should be used in all performance testing. When the negative controls show significant antimicrobial activity, the "apparent" activity of the actual antimicrobial mask specimen is not accurately demonstrated in that assay.*

Section 18.2 addresses this matter. In summary, a facemask, of the same materials of construction

(b)(4) [redacted]

4. *FDA stated that "preconditioning" of the mask is not how the device will be used by health care workers. This should not be used in performance testing protocols.*

Section 18.2 addresses this matter. In summary, no pre-conditioning of the facemasks was conducted prior to assessing the virucidal efficacy against influenza (Section 18.2).

5. *FDA stated that all testing should be done on the final finished product under conditions which simulate, as closely as possible, the actual conditions of use.*

Section 18.2 addresses this matter. In summary, virucidal efficacy of the entire, finished BioFriend™

(b)(4) [redacted]

temperature and donned on the face (Section 18.2).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

End.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Appendix 21

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B	Minutes of Teleconference Meeting for Pre-IDE Submission I090448-Filligent, Ltd. with CDRH, 30 July 2009	21-12
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Appendix A

OCT. 10. 2008 3:55PM FDA-CDRH-ODE-POS NO. 6426 P. 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Filligent Limited
C/O Mr. Ian P. Gordon
Senior Vice President
Emergo Group Incorporated
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

OCT 10 2008

Re: C080073
Device Name: FM-200-3008 BioMask
Dated: August 25, 2008
Received: September 03, 2008

Dear Mr. Gordon:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the FM-200-3008 BioMask. Based on the information provided in your submission, we believe that the FM-200-3008 BioMask falls within Title 21 of the Code of Federal Regulations (CFR) 878.4040, Surgical Apparel – Surgical Masks. A Surgical Mask is a Class II type device. Therefore you will need to submit a premarket notification [510(k)] and receive the Food and Drug Administration's (FDA's) clearance prior to marketing your device. You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act.

From the information in C080073 we understand that the FM-200-3008 BioMask has technological characteristics (i.e., presence of antimicrobial agent) that have not been cleared previously for Surgical Masks. We also note that you have indicated the FM-200-3008 BioMask for use by the public and by children, which are new user groups when compared to the current user-group (i.e., health-care workers) for FDA-cleared surgical masks. We suggest that you consider filing a pre-IDE submission for the product. For detailed information on a possible pre-IDE submission for the FM-200-3008 BioMask, please contact Dr. Sheila A. Murphey, M.D., Chief, Infection Control Devices Branch, at (240) 276-3747.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Please be advised that Title 21 Code of Federal Regulations, Part 807, Subparts A-D, requires all establishments, whether foreign or domestic, that are engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into or distribution in the U.S. to register and list with the FDA. If you have any questions regarding the registration and listing requirements, please call 240-276-0132.

Section 513(g) of the Act requires the agency to provide information about the regulatory requirements applicable to a particular type of device. The response represents my best judgment about how the product would be regulated, based upon our review of the information you have provided, including your description of the product and its intended use. My response to a 513(g) request is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution.

If you have any questions regarding this letter, please contact Dr. Sheila A. Murphey, M.D., Chief, Infection Control Devices Branch, at (240) 276-3747. For general questions please contact the Division of Small Manufacturers International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman

Christy L. Foreman, M.S.
Acting Deputy Director for Science and
Review Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Appendix B

MEETING MINUTES

TO: The Record

FROM: Elizabeth F. Claverie-Williams, M.S.

THROUGH: Sheila Murphey, M.D.
Branch Chief, Infection and Control Devices Branch

(b)(4)

[redacted]

DEVICE: FM-200/Bio-Friend™ Biomask (the "BioMask")

DEVICE DESCRIPTION:
The Bio-Friend™ medical face mask with antimicrobial properties is composed of four layers of material. The materials of the mask are shaped and folded with a weld through

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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firm states all materials used except for the antimicrobial agents, copper and zinc are used in currently marketed, FDA-cleared medical devices.

INDICATIONS for USE:
The firm states "In conjunction with good hygiene practice, the BioMask is a single use, disposable mask intended for use in infection control to minimize contamination caused by inhaled and exhaled micro-organisms and reduces the potential exposure of the wearer to blood and body fluids.

It is intended to cover the nose and mouth of the wearer to help prevent the transmission of respiratory pathogens, including those that cause influenza".

INTENDED USER GROUPS:
The firm claims the intended use is by the healthcare workers, and the general public, including children.

MEETING AGENDA:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Indications for Use and Labeling:

(b)(4)

[redacted]

8. FDA informed the firm they may submit a regular 510(k) with for a surgical face mask. FDA believes that a "face mask" for use by the general public as well as a "face mask" for pediatric use would each require a "de novo" clearance since FDA has not yet cleared any face mask with such intended uses. As described, the "Biomask" is not safe for pediatric use since it includes small pieces (on the ear loops) which would create a choking hazard for children.

9. FDA informed the firm if they want to make a "reducing TB transmission" claim, they need to provide clinical trial data and test against Mycobacterium tuberculosis not against a surrogate mycobacterium. However, FDA strongly advises against this..

GENERAL:

1. FDA will need safety and toxicology data on the release of agents from the mask due to respiration and salivary contact. Also, in the data the firm needs to describe the following:

- What amounts of agents leached off the mask

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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- Analysis of compounds to which the wearer is exposed for final safety evaluation

CONCLUSIONS and RECOMENDATIONS:

FDA encouraged the representatives of Filligent, Ltd., (Hong Kong, China) and Emergo Group, Inc. (USA) to send a supplement to the Pre-IDE submission I090448 and /or request another meeting if they have additional questions for FDA.

The firm responded by stating "Thanking" FDA and stated they would move forward with the final submission for a Class II device.

The meeting adjourned at 1100 ESDT.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Prepared by: Elizabeth F. Claverie-Williams, M.S.

Approved by: Dr. Sheila A. Murphey, M.D.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Appendix C

November 23, 2009

Ms. Melissa Mowbray-d'Arbela
Chief Executive Officer
7th Floor 69 Jervois Street
Sheung Wan, Hong Kong
Tel # (852) 2542 2400
Fax # (852) 2542 2411
Email: melissa@filligent.com

Subject: Review of I090448/S001 (FM-200/BioFriend BioMask)

Dear Ms Melissa Mowbray-d'Arbela,

We have completed the review of the information you have submitted in the pre-IDE document I090448/S001 and the list of viruses that you intend to study as part of the anti-influenza virus effectiveness of the subject device; and we are herewith providing you with the following comments. Please be advised that these comments are a general assessment of the information you have submitted and do not guarantee that the use of these comments in your 510(k) premarket notification submission will not raise new questions for the Agency.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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FDA's comments in this letter, please feel free to contact me at (301) 796-6303 or email me at: Ramesh.Panguluri@fda.hhs.gov.

Sincerely

Kapil Panguluri, Ph.D.
Microbiologist/Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health
WO66 Room 2506
10903 New Hampshire Ave.
Silver Spring, MD 20993
(301) 796-6303
Ramesh.Panguluri@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Steven Elliott

Subject: 510(k) Number K101128/S3

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NC	NSE call for PMAs
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N/A, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single-use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓

Rev. 5/12/11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. S

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Neonate/Newborn (Birth to 28 days)	✓
Infant (29 days -< 2 years old)	✓
Child (2 years -< 12 years old)	✓
Adolescent (12 years -< 18 years old)	✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)	✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	✓
Nanotechnology	✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*	✓

Regulation Number	Class*	Product Code
878.4040	II	OUK

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) INCB (Branch Code) 5/25/11 (Date)

Final Review: [signature] (Division Director) 5/26/11 (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center -- WO66-G609
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Abbreviated

K101128/S003

Date:	May 24, 2011	
To:	The Record	Office: ODE
From:	Steven Elliott Biochemistry/Physiology Reviewer	Division: DAGID
Through:	Elizabeth Claverie-Williams, Branch Chief, INCB	
510(k) Holder:	Filligent HK Limited 7/F 69 Jervois st. Sheung Wan, Hong Kong, HK	
Device Name:	BioFriend BioMask Surgical Face Mask.	
Contact:	Melissa Mowbray-D'Arbela	
Phone:	852-2542-2400	
Fax:	852-2542-2411	
Email:	melissa@filligent.com	

I. Purpose and Submission Summary

Filligent HK Limited would like to introduce the "BioFriend BioMask Surgical Face Mask." into interstate commerce. The firm has submitted a pre-market notification (PMN) [510(K)] for the device.

The firm claims that the "BioFriend BioMask Surgical Face Mask" is a Class II surgical face mask (21 CFR 878.4040), product code OUK).

The information provided in the previous submission was insufficient to determine if the subject device was substantially equivalent to the predicate and the submission was placed on hold. The sponsor has submitted an S003 response. The new information is addressed in the Section marked Deficiencies.

All deficiencies are resolved.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page OTC	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Data Report Form – Form 3654		√	

Medical Device Standards Referenced:

1. ASTM F2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks.
2. ASTM F2101: 2007 Standard Test method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask materials Using a Biological Aerosol of Staphylococcus aureus.
3. ASTM F2299: 2003 Standard Test method for determining the initial efficiency of materials used in Medical Face Masks to Penetration by Particles Using Latex Spheres.
4. ASTM F1862: 2007 Standard Test Method for Resistance of Medical Facemasks to Penetration by Synthetic Blood. (Horizontal Projection of Fixed Volume at a Known Velocity)
5. MIL-M-36954C Military Specification, Surgical Mask, Disposable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 8

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6. ISO 10993-10E:2002 Biological Evaluation of Medical Devices— Part 10 Tests for irritation and delayed-type hypersensitivity. – Listed as 2003 in the Standards Data Report for 510(k)s.
7. ISO 10993-18 Biological Evaluation of Medical Devices— Part 18 Chemical characterization of materials.
8. ASTM E1052-96 Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension.

[1]» *Reviewer Comments:*
The sponsor provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard.

- The sponsor will be asked to provide a new Standards Data Report for 510(k)s form for this standard that cites conformance to ISO 10993-10:2002 This form can be found at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf

K101128/S001: The sponsor provided an amended Standards Data Report for 510(k)s form that specified the ISO-10993-10:2002 standard.
Conclusion: This is acceptable.

The firm has provided its 510(k) Summary in section 5 of the submission:

			YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)					
	Clearly labeled "510(k) Summary"		√		
	Submitter' s name, address, phone #, a contact person		√		
	Date the summary was prepared		√		
	The name of the device/trade name/common name/classification name		√		
	An identification of the legally marketed Predicate		√		
	Description of the subject device			√	
	Statement of intended use (identical to indications for use)		√		
	Technological characteristics	if same, a summary of comparison of technological characters		√	
		If different, a summary of how do they compare to the Predicate		√	
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	√		
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination			√
		Conclusion that data demonstrate SE	√		
Required Elements for 510(k) Statement (21 CFR 807.93)					
	Signed verbatim statement				

[2]» *Reviewer Comments:*
The sponsor provided a 510(k) summary that did not contain an adequate description of the subject device. The sponsor did not indicate the subject device models or explain the differences between all subject models intended for clearance.

- The sponsor will be asked to provide an amended 510(k) summary that lists the model

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 9

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numbers of all devices intended for clearance in this submission and explains all differences between all device models and predicates. The sponsor will be asked to ensure that the amended 510(k) summary addresses all related deficiencies in this memorandum.

K101128/S001: The sponsor provided a 510(k) summary that identified all device models in the submission and contained a sufficient comparison to the predicate device. However the 510(k) summary contained the following ambiguous statements:

"Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

"These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:

  Replace "biologicals" with "viruses."

  Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

  Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested. The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

K101128/S002: The sponsor provided an amended 510(k) summary. The modifications made by the sponsor appropriately addressed the FDA requests.
The sponsor provided the exact scientific strain identification for Avian Influenza H9N2: Influenza A/Turkey/Wisconsin/1966.
Conclusion: This is acceptable.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 10

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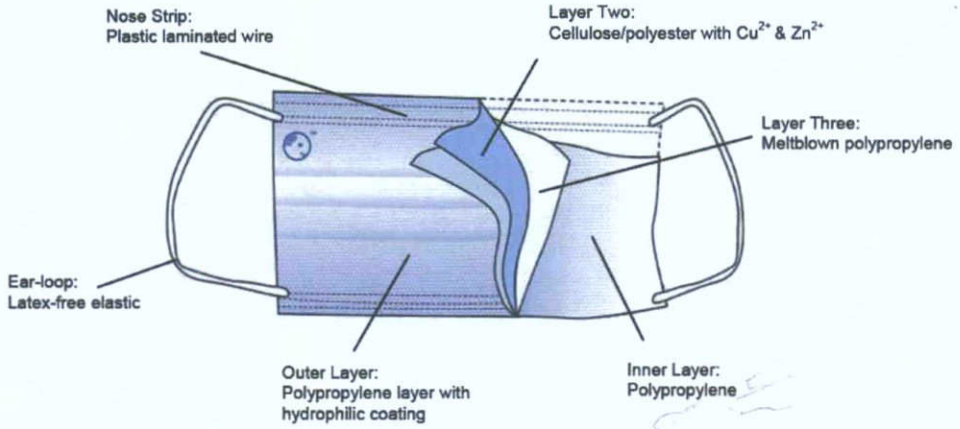
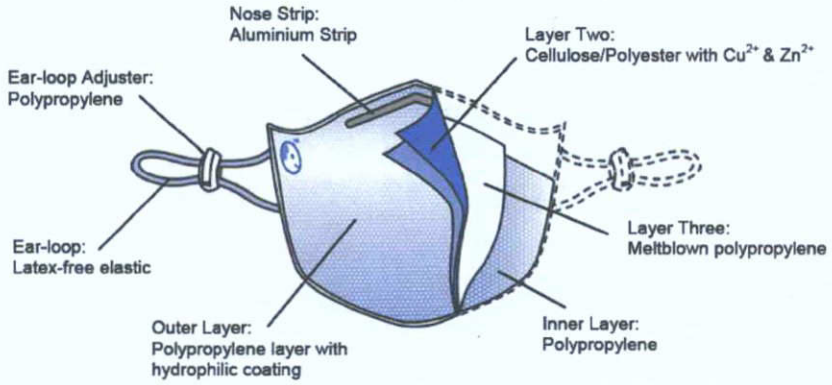
	Yes	No	N/A
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		√	

The sponsor provided the following description:
Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. The outer layer is coated with a hydrophilic plastic. The second layer is treated with copper and zinc. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip. One model is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard "comfort" features such ear adjusters and an anti-fog nose insert.

Universal BF-200-2001:



Premium BF-200-3013



Mode of Action:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 11

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(b)(4)

[3]» *Reviewer Comments:*
The sponsor has stated that Citric acid lowers the pH of its environment, but did not indicate the pH on the exterior surface of the mask, or the pH required for the claimed deactivation of specific influenza strains. This information is required to effectively determine the antimicrobial effect of Citric Acid on the mask surface.
The sponsor will be asked to indicate the pH on the exterior surface of the mask, explain how this pH was determined and provide acceptance criteria (include pH range) for the pH of the mask exterior.

K101128/S001: The sponsor studied the activity of citric acid in solution against influenza virus and stated

(b)(4)

(b)(4)

Conclusion: This is acceptable

[4]» *Reviewer Comments:*
The sponsor has described Both BioFriend BioMask devices as having anti-viral activity against influenza A and B strains. However, the relative roles of the three potentially antiviral compounds are not clearly delineated and the minimal inhibitory concentration (MEC) of the antimicrobial agents is not provided.

- The sponsor will be asked to describe the specific mode of action (state both the target molecule on the influenza virus and suppression/denaturing interaction with specific

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antimicrobial agent) and identify the magnitude of the contribution of the antimicrobial effect for each agent.

(b)(4)

[redacted]

Conclusion: This is acceptable.

[5]» *Reviewer Comments:*

(b)(4)

[redacted]

The studies performed to determine the MEC values are again those described briefly under question 3.

(b)(4)

[redacted]

into the material. However, the critical value for the BioMask is the antiviral activity of the complete and final device, not of its layers.

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The sponsor's description of "synergistic activity" among the three agents is not yet supported. There is no

(b)(4)

The sponsor has not demonstrated any synergistic performance between any of the antiviral agents.

(b)(4)

Conclusion: This is acceptable.

In response to the FDA's email request for additional descriptive information April 26, 2010, the sponsor provided MSDS reports for the following mask components:

(b)(4)

Device Specifications:
In response to the FDA's email request for additional descriptive information April 26, 2010, the sponsor provided the following dimensions for the subject masks:

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

These studies between them demonstrate that the citric acid layer alone in this device provides somewhat inconsistent anti-influenza function not always achieving a 4 $\log_{10}$ reduction by itself. The copper/zinc layer, on the other hand, is completely unable to achieve a 4 $\log_{10}$ reduction of an influenza virus challenge on its own but is shown in this study to contribute to the overall antiviral efficacy of this device. This effect of the copper/zinc layer cannot be called synergistic on the basis of the limited data on mechanisms presented in this file but does appear to contribute to the overall efficacy of the device in an additive manner. This issue is resolved.

Conclusion: This is acceptable.

(b)(4)

[redacted]

[1] Based on average total surface area of 288 cm^2
[2] min and max as calculated from the acceptance criteria

IV. Indications for Use

The sponsor provided the following information in the Indication for Use Statement:

Device Name:

BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001 and Premium BF-200-3013

Indications for Use:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as during dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

The sponsor indicated over-the-counter use.

[7]»*Reviewer's Comments:*

The sponsor provided an Indication for Use (IFU) statement that was deficient in the following areas:

A. The sponsor did not list the model numbers of the subject device. The sponsor should clearly specify all device models and state their respective model numbers.

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- The sponsor will be asked to provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. The sponsor will be asked to include a description of the differing features between model numbers.

K101128/S001: The sponsor provided an IFU statement with an adequate description of all device models.

Conclusion: This is acceptable.

B. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007.
   - The sponsor will be asked to revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

K101128/S001: The sponsor provided an IFU statement that identified all claimed antiviral agents and indicated there intended purposes. However the IFU statement contained the following ambiguous statements:

"Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

"These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:

  Replace "biologicals" with "viruses."

  Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

  Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested. The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

K101128/S002: The sponsor amended the IFU to read:

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"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses:...."
This change was reflected in the labeling and 510(k) summary.
The sponsor replaced biologicals with viruses and removed the statement that the devices protect the wearer from the splash and spray of blood and bodily fluids
Conclusion: This is acceptable.

C. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures."
   - The sponsor will be asked to revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

K101128/S001: The sponsor provided an IFU statement that replaced removed the language not found in 21 CFR 878.4040 and replaced it with: "They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and body fluids." The last sentence of this statement is addressed in the above deficiency and the other content of this statement is acceptable.
Conclusion: This is acceptable.

D. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only."
   - The sponsor will be asked to remove the above statement from the IFU; it has not been supported by performance testing.

K101128/S001: The sponsor removed this statement from the IFU.
Conclusion: This is acceptable.

E. The Indication for Use (IFU) statement did not list the influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask.
   - The sponsor will be asked to include the influenza virus strains that have been shown to be adequately reduced (>4log reduction) by the activity of the mask in the IFU statement.

K101128/S001: The sponsor included the tested viruses on the IFU statement.
Conclusion: This is acceptable.

F. The revised IFU statement should address all listed deficiencies.

K101128/S001: The sponsor has not demonstrated the antiviral performance of the copper acetate and zinc acetate in the final finished subject device.

- The sponsor will be asked to provide performance data using the final finished product that demonstrates the antiviral performance of zinc acetate and copper acetate on the claimed viruses or remove all performance claims of these compounds from the IFU and all device labeling.

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K101128/S002: The sponsor provided data that supports the antiviral, performance of zinc and copper on the mask. The IFU statement is now acceptable.
Conclusion: This is acceptable.

V. Predicate Device Comparison

The firm provided the following information for comparison of the submission with the predicate device:

(b)(4)

[redacted]

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(b)(4)

[redacted]

VI. Labeling

The sponsor provided the package labeling (individual package and box) for both mask models. Samples of the labeling are included below:

The sponsor included the following instructions on the labeling:

FITTING INSTRUCTIONS

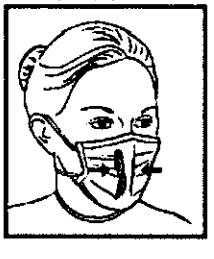
PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask

1 Pull loops around ears.

2 Expand mask over nose and under chin.

3 Press forefingers down on both sides of nose.

4 Check for snug fit and comfort.



Replace if damaged or soiled with blood or other bodily fluids.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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The following labeling was found as an online brochure:
http://www.filligent.com/uploads/file/BioFriend%20Brochure%20-%20July%2009%20-%20English.pdf

BIOMASK

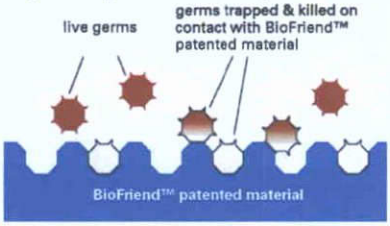
BioFriend's revolutionary, patented technology traps and kills bacteria and viruses on contact AND allows you to breathe normally:

- Traps and kills 99.9% of harmful germs
- Superior breathability & comfort
- Self-sanitizing for ALL-DAY WEAR
- Reduces cross-contamination of hands and surfaces
- Standard and small sizes

***Kills germs including those that cause Influenza A, Swine Flu, Bird Flu, common colds, measles, MRSA, pneumonia and SARS.**

BioFriend™ traps microbes by mimicking the sites on human cells to which they normally attach, then, destroys them by disrupting their surfaces (viruses) or cell walls (bacteria).

Replace after 12 hours of active wear or earlier, if damaged or soiled with blood or bodily fluids.



Single Use Package Labeling: from S003 submission:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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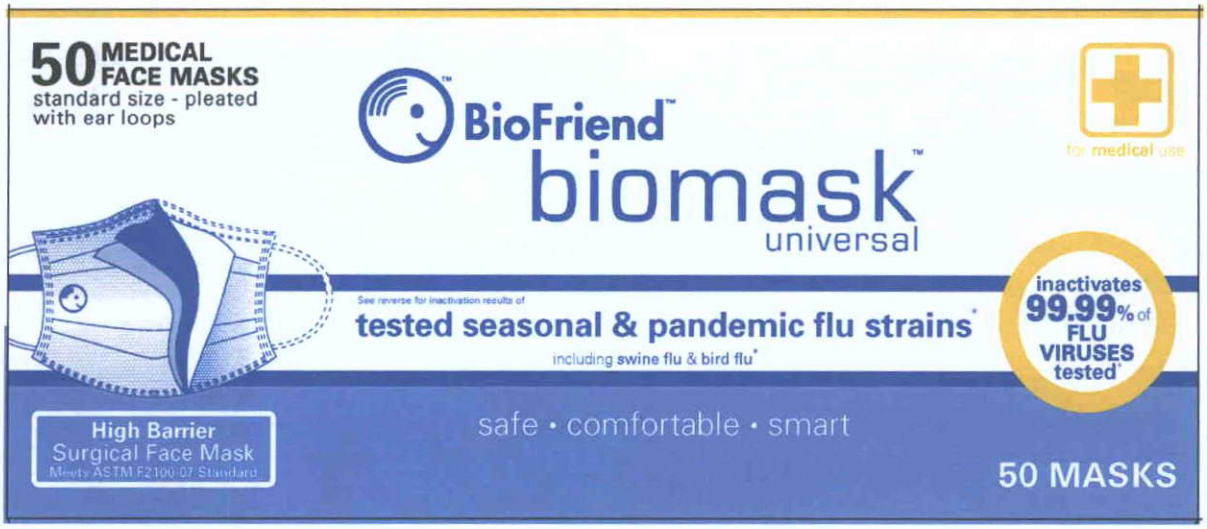
BioFriend™ BioMask™ Model: Universal BF-200-2001A

Box – Front and Back Panel



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 23

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BioFriend™ BioMask™ Model: Universal BF-200-2001A

Box – Side Panel 1

BioFriend™
biomask™
universal

FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask.

1 Put loops around ears.
2 Adjust mask over nose & under chin.
3 Press forefingers down on both sides of nose.
4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

DISPOSABLE • SINGLE USE ONLY

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the outer surface of the mask. The first and second layers of the mask are treated with different compounds that inactivate influenza viruses.

* **Inactivates 99.99% of the following tested influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal	Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human, B/Florida/4/2006 Human, B/Lee/40
Pandemic	**Pandemic H1N1, A/California/07/09** Human (H2N2), A/2/Japan/305/57
Avian	Avian (H5N1), NIBRG-14 Duck (H5N2), A/Duck/PA/10218/84 Avian (H9N2), Turkey/Wisconsin/66
Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

Powered by BioFriend™ technology.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Box – Side Panel 2

BioFriend™
biomask™
universal

DISPOSABLE
SINGLE USE ONLY

- Safe, smart & simple
- Comfortable face-design

inactivates **99.99%** of **H1N1** influenza virus tested*

INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill inactivate **99.99% of tested strains of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, H2N2 (A/2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in-vitro testing results and any clinical event has not been tested.

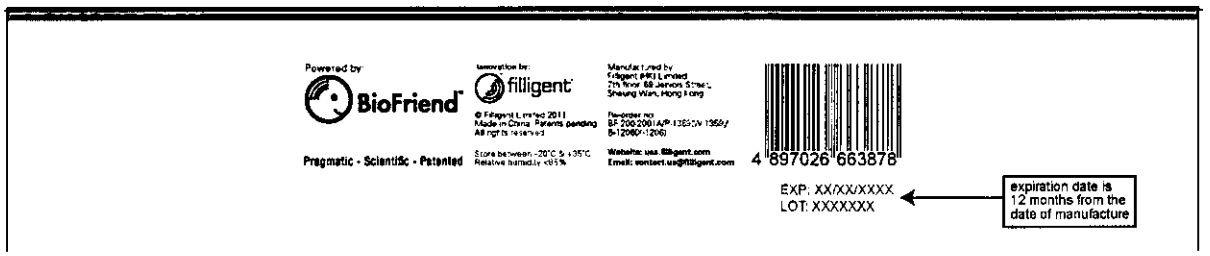
There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

WARNINGS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- Do not use if hypersensitive to copper or zinc.
- Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately.
- If mask becomes soiled please change to a new mask as the anti-microbial agents may not be effective.
- This mask does not contain natural rubber latex.
- For use in medical settings only.
- For adult use only.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Box – Bottom Flap

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.



The sponsor also provided labeling for BioFriend™ BioMask™ Model: Premium BF-200-3013A. It was identical except for the mask diagram and instructions for wear (it is a different style mask).

[8]» *Reviewer Comments*:

The sponsor provided labeling that contained the following deficiencies:

A. The sponsor provided labeling that makes broad claims about the performance of the device against influenza viruses. These claims include but are not limited to: "Inactivation of 99.99% of H1N1 influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of <u>all</u> influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim.
   - The sponsor will be asked to provide labeling that <u>only</u> includes antiviral performance claims on virus strains that demonstrated a 4 log or greater reduction during in-vitro testing.
   - In addition, the sponsor will be asked to provide labeling that clearly states that the in vitro antiviral activity demonstrated was only against single isolates of selected influenza virus strains.

K101128/S001: The sponsor stated that the labeling has been revised to include only virucidal performance claims relating solely to the tested virus strains, and for those that demonstrated the necessary virucidal reduction during *in vitro* testing on 5 minutes contact with the surface of the mask

Conclusion: This is acceptable.

B. The sponsor provided labeling with the claim: "Kills influenza Viruses on Contact." This claim implies an instantaneous inactivation of influenza which has not been substantiated.
   - The sponsor will be asked to remove the claim: "Kills influenza Viruses on Contact" from all labeling.

K101128/S001: The sponsor removed this claim from labeling.

Conclusion: This is acceptable.

C. The sponsor provided labeling with the claim: "BioMask kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file.
   - The sponsor will be asked to revise the above labeling claim to accurately reflect the performance data.

K101128/S001: The sponsor used revised wording: "Kills (inactivates) 99.99% of the following tested Influenza viruses on 5 minutes contact with the surface of the face mask, as tested in laboratories" in the labeling.

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Conclusion: This is acceptable.

D. The sponsor included the Indication for Use (IFU) statement in the labeling. Reviewer comments 6 addresses the IFU related deficiencies.

- The sponsor will be asked to revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiency 6.

K101128/S001: The sponsor submitted an amended IFU that was deficient in several areas.

- The sponsor will be asked to include these corrections in labeling.

Conclusion: This is acceptable.

E. The statement: "HOW IT WORKS: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported by performance data.

- The sponsor will be asked to provide supporting data or revise/remove this claim.

K101128/S001: The sponsor has not provided sufficient data to support this claim.

- The sponsor will be asked to provide supporting data or revise/remove this claim.

K101128/S002: The sponsor provided performance testing that supports this claim and demonstrates that fluid and viruses can be draw to the inner layers of the mask and deactivated by the copper/zinc inner layer.

Conclusion: This is acceptable.

F. The sponsor will be asked to include the following statement: No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from influenza infection."

K101128/S001: The sponsor provided labeling that includes the above statement.

Conclusion: This is acceptable.

G. The sponsor will be asked to address the following issues with the provided labeling:

i. Please add to the Warnings/Contraindications section a Caution that patients with hypersensitivity to citric acid, copper or zinc should not use this device.

K101128/S002: The cautionary statement, "Do not use if hypersensitive to copper or zinc" has been added to the labeling as requested.

Conclusion: This is acceptable.

ii. Please remove all symbols from the labeling of this device unless they are accompanied by the English language explanation of the symbol.

K101128/S002: All symbols on the labeling of the device are now accompanied by English language explanations of the relevant symbols, or have been removed entirely.

Conclusion: This is acceptable.

iii. The "Premium" BioMask should add the Caution that the small "ear adjuster" beads may pose a choking hazard to young children if separated from the device.

K101128/S002: The cautionary statement, "Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately," has been added to the labeling of the Premium BioFriend™ BioMask™ surgical facemask.

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Conclusion: This is acceptable.

iv. Please place the word "tested" in normal or larger print in the phrases below (as indicated in red) to clarify to users that only a few (18) strains of influenza have been tested against this mask.

Kills 99.9% of tested Flu Viruses tested *"
"Inactivates 99.99% of tested H1N1 influenza virus tested*"
K101128/S002: The sponsor provided labeling to appropriately address this issue.
Conclusion: This is acceptable.

v. The phrase "Seasonal and pandemic flu strains*including swine flu and bird flu*" appears to be too broad and deciphering the significance of the asterixis is not clear to the reader. This phrase should be revised. Adding "testing" or "tested" at the beginning could be considered.
K101128/S002: The labeling phrase, "seasonal and pandemic flu strains* including swine flu and bird flu*" has been revised to "tested seasonal and pandemic flu strains* including swine flu and bird flu*".
Conclusion: This is acceptable.

vi. "Protective" without further explanation implies a claim for protection against the disease influenza. This should be revised for clarity or deleted.
K101128/S002: "Protective" has been removed from the packaging as requested and amended to "high barrier protection," in reference to the mask being a High Barrier Surgical Face Mask meeting ASTM F2100-07 Standards.
Conclusion: This is acceptable.

vii. "Part of a range of innovative products" is not part of this submission and so should not appear in the labeling for this specific device. This phrase should be deleted.
K101128/S002: The phrase "Part of a range of innovative products" has been deleted from the device labeling as requested.

viii. The statement "How it works: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported. Please provide supporting data or remove this claim. The sponsor has not provided data to adequately support this claim yet; it should be deleted.
K101128/S002: Appropriate data has been provided to support this claim.
Conclusion: This is acceptable.

ix. The phrase "†when used as intended" is vague and confusing as a free-standing phrase. It should be explained in detail or deleted.
K101128/S002: The phrase "† when used as intended," has been deleted from the labeling as requested.
Conclusion: This is acceptable.

x. The phrase "This mask does not contain natural latex" needs to be revised to say "natural rubber latex" for accuracy.
K101128/S002: The phrase "This mask does not contain natural latex" has been revised to, "This mask does not contain natural rubber latex" as requested.
Conclusion: This is acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

xi. The claim "easy breathing" is a vague, ambiguous claim that could be misinterpreted. This should be removed from the labeling.
K101128/S002: The "easy breathing" claim was removed from the labeling as requested.
Conclusion: This is acceptable.

xii. The sponsor provided labeling in the S002 submission that contained the following labeling concerns:

The following objectionable and misleading phrases remain in the BioMask labeling:

- "kills **99.99%** of FLU VIRUSES tested*"
- "tested **seasonal & pandemic flu strains***"
- "inactivates **99.99%** of **H1N1** influenza virus tested*
- **"Kills (inactivates) 99.99%** of the following tested **influenza viruses** on 5 minutes contact..."
- **"99.99% of influenza viruses"**
- The effect of the bolding and font size used is to imply **"kills 99.99% of flu viruses"** and **"inactivates 99.99% of H1N1" influenza viruses.** Such claims are incorrect. The sponsor should be informed that FDA considers that the sponsor's use of bolding and font size changes to create misleading claims in its labeling. These statements should be revised. The sponsor may either "bold" or increase the font size for "tested" in all of these phrases to make them equivalent to the rest of the text.
- Where the sponsor has "bolded" the phrase **"99.99% of influenza viruses"** in the middle of a long paragraph, it should either remove the "bold" font or replace it with **"99.99% of tested strains of influenza viruses"**.
- On some box panels, the sponsor uses the term "high barrier protection" without the ASTM F2100-07 Standard reference. The sponsor should be asked to either remove the isolated phrase "high barrier protection" or to revise it wherever it is used to remove "protection" and include "meeting ASTM F2100-07 Standard".
- The FDA guidance document on Surgical Masks does not discuss or advise claims based on a perception of "cool" for a Delta-P value of 2 to 3, much less an extrapolation to a claim for "easy breathing". This claim is vague and open to misinterpretation. As previously requested, this claim should be deleted.

These issues were addressed through interactive review and the sponsor provided amended labeling that appropriately addressed all of the above concerns.
Conclusion: This is acceptable.

[9]» *Reviewer Comments:*
The online brochure contains numerous claims associated with a BioMask device that appears to be the subject of the submission. These claims are not substantiated by data in this 510(k) submission. The claims include:
BioFriend's revolutionary, patented technology traps and kills bacteria and viruses on contact AND allows you to breathe normally:
• Traps and kills 99.9% of harmful germs
• Superior breathability & comfort
• Self-sanitizing for ALL-DAY WEAR
• Reduces cross-contamination of hands and surfaces
• Standard and small sizes
*Kills germs including those that cause Influenza A, Swine Flu, Bird Flu, common colds, measles, MRSA, pneumonia and SARS.
BioFriend™ traps microbes by mimicking the sites on human cells to which they normally attach, then, destroys them by disrupting their surfaces (viruses) or cell walls (bacteria).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

also evaluate the pH of the outer mask layer and would analytically assess the amounts of citric acid, copper and zinc remaining in the BioMask. This is addressed in reviewer's comment 11-C.

Conclusion: This is acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

E. *K101128/S001:* The sponsor will be asked to provide a shelf life test report lists all device properties evaluated with the shelf life testing. For each tested property, the sponsor will be asked to provide:

(b)(4)

[redacted]

Conclusion: This is acceptable.

(b)(4)

[redacted]

The provided device performance is considered adequate for the performance claim.

VIII. Biocompatibility
Discussed in Performance Testing – Animal. Refer to Section XI.

IX. Software
N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
N/A

XI. Performance Testing – Bench
The sponsor provided reports for the following performance tests:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

	Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.	determined that the mask meets the High Barrier Class facemask requirements of ≥ 98.0% (ASTM F2100).

(b)(4)

[redacted]

The conclusions of the above performance tests are acceptable.

Safety/Toxicology

The sponsor was advised, in pre-submission interactions, to provide data on the release of the antimicrobial agents from the face masks due to respiration and salivary contact in addition to performing the usual assessment of biocompatibility for a skin-contacting device. The sponsor did not request specific advice on test methods to be used for such studies and did not provide any proposed test methods for such studies to the agency for comment.

(b)(4)

[redacted]

Simulated Respiration

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 33

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

incubations compared to 1 hour incubations. The sponsor stated "there was ample solvent contained on the pads throughout the duration of the challenge time to render the data valid".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

35

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

In Vitro Antimicrobial Performance Data

In vitro anti-viral performance of the BioMask was studied with only the Premium convex mask model and an untreated

(b)(4)

[redacted]

The neutralizer medium contained Minimal Essential Medium (MEM), 1% fetal bovine calf serum, 0.375% $NaHCO_3$, 5% HEPES and 1mM EDTA.

(b)(4)

[redacted]

* No virus was detected; the theoretical titer was determined based on the Poisson distribution.
Results presented are the average of three replicates.

(b)(4)

[redacted]

[12]* *Reviewer Comments:*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4)

K101128/S001: The sponsor refers to its response to FDA question 5 on the determination of the MEC values. The sponsor then points out that the dynamic air flow study showed only minimal release of citric

(b)(4)

antiviral agents should not create a hazard.

The sponsor argues that because any citric acid, copper or zinc which would leach out of the BioMask due to "saturation" during use would still remain within the mask, there is no need to be concerned that .

(b)(4)

Conclusion: This is acceptable.

[13]» *Reviewer Comments:*

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

K101128/S001: The sponsor has presented a fairly complete discussion of the potential toxicity of the various components of the BioMask. The sponsor has included published human toxicology data in the discussions, as well as the prior rat ingestion toxicity levels. The sponsor reported the studies which it had performed and their results.

(b)(4)

[redacted]

Citric Acid

FDA recognizes Citric acid as GRAS and which is a component of many orally ingested foods and drugs. Citric acid is a demonstrated inducer of cough and has been used for this purpose in diagnostic bronchoscopy for many years. This effect is reversible. The level of citric acid used to induce coughing in

(b)(4)

[redacted]

the mask will probably "extract" citric acid almost as efficiently as saline.

(b)(4)

[redacted]

CI Reactive Blue 21

(b)(4)

[redacted]

Copper

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) [redacted]

The sponsor states also that a personal communication from the ACGIH reported that welders developed altered taste perception when exposed to copper fume at levels of 1–3 mg.m^3 for short periods. However, exposure to levels of copper fume 0f 0.02 to 0.04 mg/m^3 did not cause symptoms. Another "personal correspondence" to the ACGIH is said to report that workers exposed to copper fumes up to 0.4 mg/m^3 did not experience "ill effects". It should be noted that PEL are determined for an average 8 hour exposure.

(b)(4) [redacted]

wearer. This will assume also, however, that the sponsor adds the suggested caution to those few persons apparently sensitized to either copper or zinc.

Zinc

Zinc is also a widely dispersed element and it is an essential human nutrient. The sponsor states that there

(b)(4) [redacted]

of zinc in the BioMask do not appear to pose a predictable hazard to the wearer of this device. Again, the label caution that zinc-sensitized persons avoid the use of this device is needed.

The additional data and discussion provided resolve the question of inadequate safety data for the BioMask

(b)(4) [redacted]

K101128/S002: The sponsor states that, because the Aspen Research Corporation testing did not provide

(b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

Conclusion: This is acceptable.

- Please discuss what could happen if citric acid-containing fluid from the mask were to be inhaled or aspirated into the respiratory tract or swallowed by a wearer of the device, especially a wearer with underlying bronchoconstricting disease.

(b)(4)

Conclusion: This is acceptable.

[14]» *Reviewer Comments:*

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

	Isolate	Initial Viral Load (Log_{10} $TCID_{50}$)	Average Log Reduction ± 95% CI for Average of 3 replicates Nov, 2010	Average Log Reduction ±95% CI calculated for 3 replicates Apr, 2010

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

The above Table presents exactly the same data analyzed two different ways. The above Table also clearly shows a significant effect of the initial challenge viral titer on the results obtained with this assay. The

(b)(4)

[redacted]

The BioMask device brings innate nonspecific effects to an antiviral performance assay which must be accounted for in the design and conduct of the assays. In this case, it is necessary to insure a high enough

(b)(4)

[redacted]

The data below is the actual log reduction for each replicate instead of the average of the three replicates with a Confidence Interval included.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 46

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Conclusion: This is acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 47

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(b)(4)

[redacted]

XII. Performance Testing – Animal

The sponsor provided primary skin irritation testing performed in a manner consistent with ISO 10993-10:2002

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

standards that demonstrates the sensitivity of the irritation assay.

(b)(4)

[redacted]

Conclusion: This is acceptable.

XIII. Performance Testing – Clinical
N/A

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		√	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		√	If **YES** = Stop **NSE**
3. Same Technological Characteristics?		√	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	√		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		√	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	√		If **NO** = Stop **NSE**
8. Performance Data Available?	√		**If NO = Request Data**
9. Data Demonstrate Equivalence?	√		Final Decision: SE

Note: Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
The IFU of the subject device addresses the antimicrobial performance of the mask against specific Influenza viruses
2. Explain why there is or is not a new effect or safety or effectiveness issue:
Safety and effectiveness can be evaluated by performance testing
3. Describe the new technological characteristics:
Presence of copper acetate, zinc acetate and citric acid in and on mask.
4. Explain how new characteristics could or could not affect safety or effectiveness:
Safety and effectiveness can be evaluated by performance testing
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Performance of the device can be evaluated using traditional mask performance tests and existing methods for evaluating microbial reduction.

7. Explain why accepted scientific methods for analyzing safety and effectiveness do or don't exist.

Antimicrobial properties of the mask can be evaluated with appropriate virus titers. The persistence of these properties can be addressed with aging, leech-off studies and simulated use challenges.

8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The presence, persistence and functionality of the antimicrobial agents have been demonstrated and meet FDA expectations for an antimicrobial mask. There were no identified biocompatibility concerns.

XV. Deficiencies

All deficiencies are resolved.

[1]» The sponsor provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard.

- The sponsor will be asked to provide a new Standards Data Report for 510(k)s form for this standard that cites conformance to ISO 10993-10:2002 This form can be found at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf

K101128/S001: The sponsor provided an amended Standards Data Report for 510(k)s form that specified the ISO-10993-10:2002 standard.

Conclusion: This is acceptable.

[2]» The sponsor provided a 510(k) summary that did not contain an adequate description of the subject device. The sponsor did not indicate the subject device models or explain the differences between all subject models intended for clearance.

- The sponsor will be asked to provide an amended 510(k) summary that lists the model numbers of all devices intended for clearance in this submission and explains all differences between all device models and predicates. The sponsor will be asked to ensure that the amended 510(k) summary addresses all related deficiencies in this memorandum.

K101128/S001: The sponsor provided a 510(k) summary that identified all device models in the submission and contained a sufficient comparison to the predicate device. However the 510(k) summary contained the following ambiguous statements:

  - "Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."
  - "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."
  - "These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:
  - Replace "biologicals" with "viruses."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 50

- Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

- Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested.

The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

K101128/S002: The sponsor provided an amended 510(k) summary. The modifications made by the sponsor appropriately addressed the FDA requests.

The sponsor provided the exact scientific strain identification for Avian Influenza H9N2: Influenza A/Turkey/Wisconsin/1966.

Conclusion: This is acceptable.

(b)(4)

[redacted]

Conclusion: This is acceptable

[4]» The sponsor has described Both BioFriend BioMask devices as having anti-viral activity against influenza A and B strains. However, the relative roles of the three potentially antiviral compounds are not clearly delineated and the minimal inhibitory concentration (MEC) of the antimicrobial agents is not provided.

- The sponsor will be asked to describe the specific mode of action (state both the target molecule on the influenza virus and suppression/denaturing interaction with specific antimicrobial agent) and identify the magnitude of the contribution of the antimicrobial effect for each agent.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

Conclusion: This is acceptable.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

The highest concentrations of zinc and copper tested together were not reported to have been tested separately. There may be a mild additive effect of zinc and copper together but the data reported does not support a synergistic effect of copper and zinc together. These assays do not address interactions between copper/zinc and citric acid. They were not performed in the final finished product. They provide modest support for the claimed MEC values but do not support evidence of interactions between citric acid and copper/zinc.

(b)(4)

[redacted]

Conclusion: This is acceptable.

[6]» The sponsor will be asked to provide data to support the statement that both the viral inoculum and the citric acid on the surface of the mask are actually drawn into the inner layers of the mask during testing and use. The sponsor will be asked to provide the pH achieved in the second layer of the mask during challenge testing.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Conclusion: This is acceptable.

[7]*The sponsor provided an Indication for Use (IFU) statement that was deficient in the following areas:

A. The sponsor did not list the model numbers of the subject device. The sponsor should clearly specify all device models and state their respective model numbers.
    - The sponsor will be asked to provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. The sponsor will be asked to include a description of the differing features between model numbers.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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K101128/S001: The sponsor provided an IFU statement with an adequate description of all device models.
Conclusion: This is acceptable.

B. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007.
   - The sponsor will be asked to revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

K101128/S001: The sponsor provided an IFU statement that identified all claimed antiviral agents and indicated there intended purposes. However the IFU statement contained the following ambiguous statements:

"Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including - Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

"These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:

  Replace "biologicals" with "viruses."

  Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

  Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including - [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested. The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

K101128/S002: The sponsor amended the IFU to read:
"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses:...."
This change was reflected in the labeling and 510(k) summary.
The sponsor replaced biologicals with viruses and removed the statement that the devices protect the wearer from the splash and spray of blood and bodily fluids
Conclusion: This is acceptable.

C. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures."
   - The sponsor will be asked to revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

K101128/S001: The sponsor provided an IFU statement that replaced removed the language not found in 21 CFR 878.4040 and replaced it with: "They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and body fluids." The last sentence of this statement is addressed in the above deficiency and the other content of this statement is acceptable.

Conclusion: This is acceptable.

D. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only."
   - The sponsor will be asked to remove the above statement from the IFU; it has not been supported by performance testing.

   K101128/S001: The sponsor removed this statement from the IFU.

Conclusion: This is acceptable.

E. The Indication for Use (IFU) statement did not list the influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask.
   - The sponsor will be asked to include the influenza virus strains that have been shown to be adequately reduced (>4log reduction) by the activity of the mask in the IFU statement.

   K101128/S001: The sponsor included the tested viruses on the IFU statement.

Conclusion: This is acceptable.

F. The revised IFU statement should address all listed deficiencies.

K101128/S001: The sponsor has not demonstrated the antiviral performance of the copper acetate and zinc acetate in the final finished subject device.
- The sponsor will be asked to provide performance data using the final finished product that demonstrates the antiviral performance of zinc acetate and copper acetate on the claimed viruses or remove all performance claims of these compounds from the IFU and all device labeling.

K101128/S002: The sponsor provided data that supports the antiviral, performance of zinc and copper on the mask and The IFU statement is now acceptable.

Conclusion: This is acceptable.

[8]• *Reviewer Comments*:

The sponsor provided labeling that contained the following deficiencies:

A. The sponsor provided labeling that makes broad claims about the performance of the device against influenza viruses. These claims include but are not limited to: "Inactivation of 99.99% of H1N1 influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of <u>all</u> influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim.
   - The sponsor will be asked to provide labeling that <u>only</u> includes antiviral performance claims on virus strains that demonstrated a 4 log or greater reduction during in-vitro testing.
   - In addition, the sponsor will be asked to provide labeling that clearly states that the in vitro antiviral activity demonstrated was only against single isolates of selected influenza virus strains.

   K101128/S001: The sponsor stated that the labeling has been revised to include only virucidal performance claims relating solely to the tested virus strains, and for those that demonstrated the necessary virucidal reduction during *in vitro* testing on 5 minutes contact with the surface of the mask

Conclusion: This is acceptable.

B. The sponsor provided labeling with the claim: "Kills influenza Viruses on Contact." This claim implies an instantaneous inactivation of influenza which has not been substantiated.
   - The sponsor will be asked to remove the claim: "Kills influenza Viruses on Contact" from all labeling.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

K101128/S001: The sponsor removed this claim from labeling.
Conclusion: This is acceptable.

C. The sponsor provided labeling with the claim: "BioMask kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file.

- The sponsor will be asked to revise the above labeling claim to accurately reflect the performance data.

K101128/S001: The sponsor used revised wording: "Kills (inactivates) 99.99% of the following tested Influenza viruses on 5 minutes contact with the surface of the face mask, as tested in laboratories" in the labeling.
Conclusion: This is acceptable.

D. The sponsor included the Indication for Use (IFU) statement in the labeling. Reviewer comments 6 addresses the IFU related deficiencies.

- The sponsor will be asked to revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiency 6.

K101128/S001: The sponsor submitted an amended IFU that was deficient in several areas.

- The sponsor will be asked to include these corrections in labeling.

Conclusion: This is acceptable.

E. The statement: "HOW IT WORKS: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported by performance data.

- The sponsor will be asked to provide supporting data or revise/remove this claim.

K101128/S001: The sponsor has not provided sufficient data to support this claim.

- The sponsor will be asked to provide supporting data or revise/remove this claim.

K101128/S002: The sponsor provided performance testing that supports this claim and demonstrates that fluid and viruses can be draw to the inner layers of the mask and deactivated by the copper/zinc inner layer.

Conclusion: This is acceptable.

F. The sponsor will be asked to include the following statement: No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from influenza infection."

K101128/S001: The sponsor provided labeling that includes the above statement.
Conclusion: This is acceptable.

G. The sponsor will be asked to address the following issues with the provided labeling:

i. Please add to the Warnings/Contraindications section a Caution that patients with hypersensitivity to citric acid, copper or zinc should not use this device.

K101128/S002: The cautionary statement, "Do not use if hypersensitive to copper or zinc" has been added to the labeling as requested.

Conclusion: This is acceptable.

ii. Please remove all symbols from the labeling of this device unless they are accompanied by the English language explanation of the symbol.

K101128/S002: All symbols on the labeling of the device are now accompanied by English language explanations of the relevant symbols, or have been removed entirely.

Conclusion: This is acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

iii. The "Premium" BioMask should add the Caution that the small "ear adjuster" beads may pose a choking hazard to young children if separated from the device.

K101128/S002: The cautionary statement, "Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately," has been added to the labeling of the Premium BioFriend™ BioMask™ surgical facemask.

Conclusion: This is acceptable.

iv. Please place the word "tested" in normal or larger print in the phrases below (as indicated in red) to clarify to users that only a few (18) strains of influenza have been tested against this mask.

Kills 99.9% of tested Flu Viruses tested *"
"Inactivates 99.99% of tested H1N1 influenza virus tested*"

K101128/S002: The sponsor provided labeling to appropriately address this issue.

Conclusion: This is acceptable.

v. The phrase "Seasonal and pandemic flu strains*including swine flu and bird flu*" appears to be too broad and deciphering the significance of the asterixis is not clear to the reader. This phrase should be revised. Adding "testing" or "tested" at the beginning could be considered.

K101128/S002: The labeling phrase, "seasonal and pandemic flu strains* including swine flu and bird flu*" has been revised to "tested seasonal and pandemic flu strains* including swine flu and bird flu*".

Conclusion: This is acceptable.

vi. "Protective" without further explanation implies a claim for protection against the disease influenza. This should be revised for clarity or deleted.

K101128/S002: "Protective" has been removed from the packaging as requested and amended to "high barrier protection," in reference to the mask being a High Barrier Surgical Face Mask meeting ASTM F2100-07 Standards.

Conclusion: This is acceptable.

vii. "Part of a range of innovative products" is not part of this submission and so should not appear in the labeling for this specific device. This phrase should be deleted.

K101128/S002: The phrase "Part of a range of innovative products" has been deleted from the device labeling as requested.

Conclusion: This is acceptable.

viii. The statement "How it works: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported. Please provide supporting data or remove this claim. The sponsor has not provided data to adequately support this claim yet; it should be deleted.

K101128/S002: Appropriate data has been provided to support this claim.

Conclusion: This is acceptable.

ix. The phrase "†when used as intended" is vague and confusing as a free-standing phrase. It should be explained in detail or deleted.

K101128/S002: The phrase "† when used as intended," has been deleted from the labeling as requested.

Conclusion: This is acceptable.

x. The phrase "This mask does not contain natural latex" needs to be revised to say "natural rubber latex" for accuracy.

K101128/S002: The phrase "This mask does not contain natural latex" has been revised to, "This mask does not contain natural rubber latex" as requested.

Conclusion: This is acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

xi. The claim "easy breathing" is a vague, ambiguous claim that could be misinterpreted. This should be removed from the labeling.

K101128/S002: The "easy breathing" claim was removed from the labeling as requested.

Conclusion: This is acceptable.

xii. The sponsor provided labeling in the S002 submission that contained the following labeling concerns:
The following objectionable and misleading phrases remain in the BioMask labeling:

- "kills **99.99%** of FLU VIRUSES tested*"
- "tested **seasonal & pandemic flu strains***"
- "inactivates **99.99%** of **H1N1** influenza virus tested*
- **"Kills (inactivates) 99.99%** of the following tested **influenza viruses** on 5 minutes contact..."
- **"99.99% of influenza viruses"**
- The effect of the bolding and font size used is to imply **"kills 99.99% of flu viruses"** and **"inactivates 99.99% of H1N1" influenza viruses.** Such claims are incorrect. The sponsor should be informed that FDA considers that the sponsor's use of bolding and font size changes to create misleading claims in its labeling. These statements should be revised. The sponsor may either "bold" or increase the font size for "tested" in all of these phrases to make them equivalent to the rest of the text.
- Where the sponsor has "bolded" the phrase **"99.99% of influenza viruses"** in the middle of a long paragraph, it should either remove the "bold" font or replace it with **"99.99% of tested strains of influenza viruses"**.
- On some box panels, the sponsor uses the term "high barrier protection" without the ASTM F2100-07 Standard reference. The sponsor should be asked to either remove the isolated phrase "high barrier protection" or to revise it wherever it is used to remove "protection" and include "meeting ASTM F2100-07 Standard".
- The FDA guidance document on Surgical Masks does not discuss or advise claims based on a perception of "cool" for a Delta-P value of 2 to 3, much less an extrapolation to a claim for "easy breathing". This claim is vague and open to misinterpretation. As previously requested, this claim should be deleted.

These issues were addressed through interactive review and the sponsor provided amended labeling that appropriately addressed all of the above concerns.

Conclusion: This is acceptable.

(b)(4)

[redacted]

- The sponsor will be asked to please clarify if these claims are intended for the subject of this submission as they have not been supported by data.

  K101128/S001: The sponsor stated that the above claims are associated with another product, not the subject of the submission.

Conclusion: This is acceptable.

[10]* The sponsor did not indicate the shelf life of the subject device.

- The sponsor will be asked to indicate the shelf life of the subject device.

  K101128/S001: The sponsor stated that they intended to label the subject devices with an initial shelf life of one year and continue testing at 6 month intervals to obtain a shelf life of 3-5 years.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8114

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Conclusion: This is acceptable.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Conclusion: This is acceptable.

D. The sponsor should evaluate the persistence of the antiviral agents in the subject device. The sponsor will be recommended to provide test reports determining the actual levels of the antiviral agents through the shelf life of the device.

(b)(4)

[redacted]

Conclusion: This is acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 61

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

E. *K101128/S001:* The sponsor will be asked to provide a shelf life test report lists all device properties evaluated with the shelf life testing. For each tested property, the sponsor will be asked to provide:

(b)(4)

[redacted]

Conclusion: This is acceptable.

(b)(4)

[redacted]

Conclusion: This is acceptable.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 63

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Conclusion: This is acceptable.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 64

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

Conclusion: This is acceptable.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 65

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 66

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Conclusion: This is acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 68

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

Conclusion: This is acceptable.

S002 Deficiencies:

1 – The sponsor provided an Indications-for-Use Statement, 510(k) Summary and labeling that use the term "kill" for viruses. The FDA believed that this term is not acceptable for viruses.

- The sponsor will be asked to provide amended Indications-for-Use Statement, 510(k) Summary and labeling that removes the term "kill" and only uses the term "inactivate".

K101128/S003: The sponsor provided amended IFU statement, 510(k) summary and labeling that used "inactivate" instead of "kill" for its action on the claimed viruses. The labeling included in the S003 submission is considered acceptable, all previous labeling in the submission is not.

This is acceptable.

2 – FDA has released a new product code for the subject device.

- The sponsor will be asked to amend the 510(k) summary by removing the FXX product code and replacing it with OUK.

K101128/S003: The sponsor provided amended IFU statement, 510(k) summary and labeling that used "inactivate" instead of "kill" for its action on the claimed viruses. The labeling included in the S003 submission is considered acceptable, all previous labeling in the submission is not.

This is acceptable.

3 – The sponsor has not provided testing that fully addresses the use conditions of the subject device. The sponsor provided leach-off data with simulated salivary contact, but the antiviral performance of the subject device for extended use with soil and/or saliva on the surface of the mask and repeated viral challenges has not been determined.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Contact History:

- The sponsor was contacted on April 26, 2010 regarding additional submission material.
- The sponsor replied on April 26, 2010.
- The sponsor was contacted on April 27 with a request for supplemental material.
- The sponsor replied to the request on May 5, 2010.
- A request for additional information was mailed to the firm May 21, 2010.
- A request for additional information was emailed and faxed to the firm December 29, 2010.
- A request for information through interactive review was sent to the sponsor February 22, 2011
- A request for information through interactive review was sent to the sponsor February 25, 2011
- A response to the February 2011 requests for information was provided by the sponsor March 3, 2011
- A request for additional information was emailed and faxed to the firm March 4, 2011.
- A request for additional information was emailed and faxed to the firm March 4, 2011.
- Teleconference with sponsor on repeated insult/simulated use testing March 7, 2011
- Teleconference with sponsor on repeated insult/simulated use testing March 17, 2011
- Teleconference with sponsor on submission recommendations May 12, 2011

Recommendation:

SE

Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Mask.
Regulatory Class: Class II
Product Code: OUK

Steven Elliott, MS.
Reviewer

May 24, 2011
Date

Elizabeth Claverie-Williams, MS
Branch Chief

25 May 2011
Date

5/26/11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

70

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Steven Elliott

Subject: 510(k) Number K101128/S3

To: The Record

Please list CTS decision code RS Incomplete Response 3/15/11

- [x] Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- [ ] Hold (Additional Information or Telephone Hold).
- [ ] Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	Class*	Product Code
878 4040	II	OUK

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

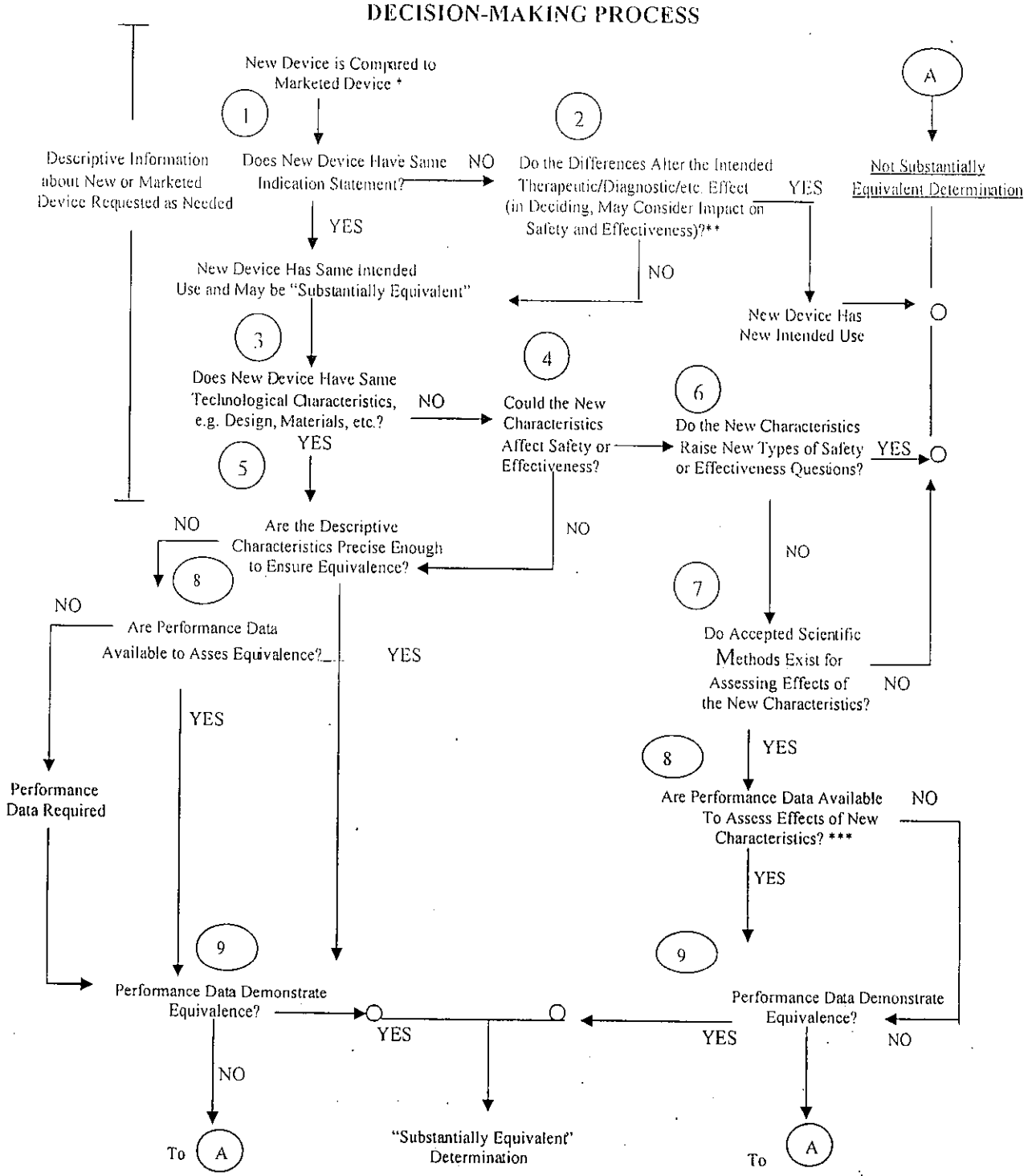
Review: Elizabeth F. Mansfield (Branch Chief) — INCB (Branch Code) — 3/15-/11 (Date)

Final Review: _____ (Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center -- WO66-G609
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Abbreviated

3-15-11

K101128/S003

Date:	March 15, 2011	
To:	The Record	Office: ODE
From:	Steven Elliott Biochemistry/Physiology Reviewer	Division: DAGID
Through:	Elizabeth Claverie-Williams, Branch Chief, INCB	
510(k) Holder:	Filligent HK Limited 7/F 69 Jervois st. Sheung Wan, Hong Kong, HK	
Device Name:	BioFriend BioMask Surgical Face Mask.	
Contact:	Melissa Mowbray-D'Arbela	
Phone:	852-2542-2400	
Fax:	852-2542-2411	
Email:	melissa@filligent.com	

I. Purpose and Submission Summary

Filligent HK Limited would like to introduce the "BioFriend BioMask Surgical Face Mask." into interstate commerce. The firm has submitted a pre-market notification (PMN) [510(K)] for the device.

The firm claims that the "BioFriend BioMask Surgical Face Mask" is a Class II surgical face mask (21 CFR 878.4040), product code OUK).

The information provided in the previous submission was insufficient to determine if the subject device was substantially equivalent to the predicate and the submission was placed on hold. The sponsor has submitted an S003 response. The new information is addressed in the Section marked Deficiencies.

Note: The S002 response contained 3 outstanding deficiencies. The sponsor did not address all deficiencies. This submission is considered an incomplete response.

Contact History:

- The sponsor was contacted on April 26, 2010 regarding additional submission material.
- The sponsor replied on April 26, 2010.
- The sponsor was contacted on April 27 with a request for supplemental material.
- The sponsor replied to the request on May 5, 2010.
- A request for additional information was mailed to the firm May 21, 2010.
- A meeting to discuss deficiencies was held June 22, 2010
- A request for additional information was emailed and faxed to the firm December 29, 2010.
- A request for information through interactive review was sent to the sponsor February 22, 2011
- A request for information through interactive review was sent to the sponsor February 25, 2011
- A response to the February 2011 requests for information was provided by the sponsor March 3, 2011
- A request for additional information was emailed and faxed to the firm march 4, 2011.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Recommendation:

It is recommended that this 510 (k) submission, K101128, be placed on HOLD pending the receipt of the above requested information.

Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Mask.
Regulatory Class: Class II
Product Code: OUK

Steven Elliott, MS
Reviewer

March 15, 2011
Date

Elizabeth Claverie-Williams, MS
Branch Chief

3/15/11
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center -- WO66-G609
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Abbreviated

K101128/S002

Date:	March 4, 2011	
To:	The Record	Office: ODE
From:	Steven Elliott Biochemistry/Physiology Reviewer	Division: DAGID
Through:	Elizabeth Claverie-Williams, Branch Chief, INCB	
510(k) Holder:	Filligent HK Limited 7/F 69 Jervois st. Sheung Wan, Hong Kong, HK	
Device Name:	BioFriend BioMask Surgical Face Mask.	
Contact:	Melissa Mowbray-D'Arbela	
Phone:	852-2542-2400	
Fax:	852-2542-2411	
Email:	melissa@filligent.com	

I. Purpose and Submission Summary

Filligent HK Limited would like to introduce the "BioFriend BioMask Surgical Face Mask." into interstate commerce. The firm has submitted a pre-market notification (PMN) [510(K)] for the device.

The firm claims that the "BioFriend BioMask Surgical Face Mask" is a Class II surgical face mask (21 CFR 878.4040), product code OUK).

The information provided in the previous submission was insufficient to determine if the subject device was substantially equivalent to the predicate and the submission was placed on hold. The sponsor has submitted an S002 response. The new information is addressed in the Section marked Deficiencies.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page OTC	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Data Report Form – Form 3654		√	

Medical Device Standards Referenced:

1. ASTM F2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks.
2. ASTM F2101: 2007 Standard Test method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask materials Using a Biological Aerosol of Staphylococcus aureus.
3. ASTM F2299: 2003 Standard Test method for determining the initial efficiency of materials used in Medical Face Masks to Penetration by Particles Using Latex Spheres.
4. ASTM F1862: 2007 Standard Test Method for Resistance of Medical Facemasks to Penetration by Synthetic Blood. (Horizontal Projection of Fixed Volume at a Known Velocity)
5. MIL-M-36954C Military Specification, Surgical Mask, Disposable.
6. ISO 10993-10E:2002 Biological Evaluation of Medical Devices— Part 10 Tests for irritation and delayed-type hypersensitivity. – Listed as 2003 in the Standards Data Report for 510(k)s.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 87

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7. ISO 10993-18 Biological Evaluation of Medical Devices— Part 18 Chemical characterization of materials.
8. ASTM E1052-96 Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension.

[1]» *Reviewer Comments:*
The sponsor provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard.

- The sponsor will be asked to provide a new Standards Data Report for 510(k)s form for this standard that cites conformance to ISO 10993-10:2002 This form can be found at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf

K101128/S001: The sponsor provided an amended Standards Data Report for 510(k)s form that specified the ISO-10993-10:2002 standard.
Conclusion: This is acceptable.

The firm has provided its 510(k) Summary in section 5 of the submission:

			YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)					
	Clearly labeled "510(k) Summary"		√		
	Submitter' s name, address, phone #, a contact person		√		
	Date the summary was prepared		√		
	The name of the device/trade name/common name/classification name		√		
	An identification of the legally marketed Predicate		√		
	Description of the subject device			√	
	Statement of intended use (identical to indications for use)		√		
	Technological characteristics	if same, a summary of comparison of technological characters		√	
		If different, a summary of how do they compare to the Predicate		√	
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	√		
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination			√
		Conclusion that data demonstrate SE	√		
Required Elements for 510(k) Statement (21 CFR 807.93)					
	Signed verbatim statement				

[2]» *Reviewer Comments:*
The sponsor provided a 510(k) summary that did not contain an adequate description of the subject device. The sponsor did not indicate the subject device models or explain the differences between all subject models intended for clearance.

- The sponsor will be asked to provide an amended 510(k) summary that lists the model numbers of all devices intended for clearance in this submission and explains all differences

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

between all device models and predicates. The sponsor will be asked to ensure that the amended 510(k) summary addresses all related deficiencies in this memorandum.

K101128/S001: The sponsor provided a 510(k) summary that identified all device models in the submission and contained a sufficient comparison to the predicate device. However the 510(k) summary contained the following ambiguous statements:

"Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

"These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:

  Replace "biologicals" with "viruses."

  Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

  Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested. The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

K101128/S002: The sponsor provided an amended 510(k) summary. The modifications made by the sponsor appropriately addressed the FDA requests.
The sponsor provided the exact scientific strain identification for Avian Influenza H9N2: Influenza A/Turkey/Wisconsin/1966.
Conclusion: This is acceptable.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	
Is the device sterile?		√	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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effect for each agent.

K101128/S001: The sponsor states that the mechanism of citric acid is the induction of viral structural changes by the denaturation of outer layer lipid proteins and "damaging the outer and peri-nuclear membranes of many enveloped virus". The sponsor states that copper and zinc inactivate viruses by damaging viral proteins, lipids and nucleic acids.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 92

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[redacted]

Device Specifications:
In response to the FDA's email request for additional descriptive information April 26, 2010, the sponsor provided the following dimensions for the subject masks:

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In response to the FDA's email request for additional descriptive information April 26, 2010, the sponsor has claimed that the materials used in the construction of the Universal BF-200-2001 and Premium BF-200-3013 are of

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K101128/S001: The sponsor has provided two types of data to support its claim of movement of a fluid challenge and of citric acid from the outermost layer into the second layer of the mask.

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more data. The sponsor will be asked to provide the following information:

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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(b)(4)

[redacted]

IV. Indications for Use
The sponsor provided the following information in the Indication for Use Statement:

Device Name:
BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001 and Premium BF-200-3013

Indications for Use:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as during dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

The sponsor indicated over-the-counter use.

[7]»*Reviewer's Comments:*
The sponsor provided an Indication for Use (IFU) statement that was deficient in the following areas:

A. The sponsor did not list the model numbers of the subject device. The sponsor should clearly specify all device models and state their respective model numbers.

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- The sponsor will be asked to provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. The sponsor will be asked to include a description of the differing features between model numbers.

K101128/S001: The sponsor provided an IFU statement with an adequate description of all device models.

Conclusion: This is acceptable.

B. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007.
   - The sponsor will be asked to revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

K101128/S001: The sponsor provided an IFU statement that identified all claimed antiviral agents and indicated there intended purposes. However the IFU statement contained the following ambiguous statements:

"Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

"These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:

  Replace "biologicals" with "viruses."

  Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

  Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested. The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

K101128/S002: The sponsor amended the IFU to read:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses:...."
This change was reflected in the labeling and 510(k) summary.
The sponsor replaced biologicals with viruses and removed the statement that the devices protect the wearer from the splash and spray of blood and bodily fluids
Conclusion: This is acceptable.

C. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures."
   - The sponsor will be asked to revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

K101128/S001: The sponsor provided an IFU statement that replaced removed the language not found in 21 CFR 878.4040 and replaced it with: "They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and body fluids." The last sentence of this statement is addressed in the above deficiency and the other content of this statement is acceptable.
Conclusion: This is acceptable.

D. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only."
   - The sponsor will be asked to remove the above statement from the IFU; it has not been supported by performance testing.

K101128/S001: The sponsor removed this statement from the IFU.
Conclusion: This is acceptable.

E. The Indication for Use (IFU) statement did not list the influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask.
   - The sponsor will be asked to include the influenza virus strains that have been shown to be adequately reduced (>4log reduction) by the activity of the mask in the IFU statement.

K101128/S001: The sponsor included the tested viruses on the IFU statement.
Conclusion: This is acceptable.

F. The revised IFU statement should address all listed deficiencies.

K101128/S001: The sponsor has not demonstrated the antiviral performance of the copper acetate and zinc acetate in the final finished subject device.

- The sponsor will be asked to provide performance data using the final finished product that demonstrates the antiviral performance of zinc acetate and copper acetate on the claimed viruses or remove all performance claims of these compounds from the IFU and all device labeling.

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K101128/S002: The sponsor provided data that supports the antiviral, performance of zinc and copper on the mask. The IFU statement is now acceptable.
Conclusion: This is acceptable.

V. Predicate Device Comparison

The firm provided the following information for comparison of the submission with the predicate device:

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[redacted]

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[redacted]

VI. Labeling

The sponsor provided the package labeling (individual package and box) for both mask models. Samples of the labeling are included below:

The sponsor included the following instructions on the labeling:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask

1 Pull loops around ears.

2 Expand mask over nose and under chin.

3 Press forefingers down on both sides of nose.

4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

The following labeling was found as an online brochure:
http://www.filligent.com/uploads/file/BioFriend%20Brochure%20-%20July%2009%20-%20English.pdf

BIOMASK

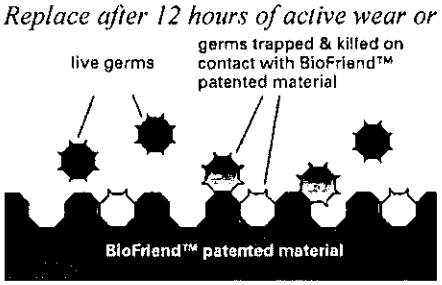
BioFriend's revolutionary, patented technology traps and kills bacteria and viruses on contact AND allows you to breathe normally:

- Traps and kills 99.9% of harmful germs
- Superior breathability & comfort
- Self-sanitizing for ALL-DAY WEAR
- Reduces cross-contamination of hands and surfaces
- Standard and small sizes

***Kills germs including those that cause Influenza A, Swine Flu, Bird Flu, common colds, measles, MRSA, pneumonia and SARS.**

BioFriend™ traps microbes by mimicking the sites on human cells to which they normally attach, then, destroys them by disrupting their surfaces (viruses) or cell walls (bacteria).

Replace after 12 hours of active wear or earlier, if damaged or soiled with blood or bodily fluids.



Single Use Package Labeling:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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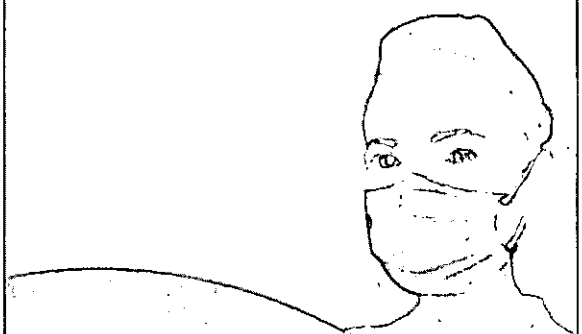
EXP: DD/MM/YY
LOT: XXXXXX

SURGICAL FACE MASK
1 standard size - pleated
with ear loops

BioFriend™
biomask™
universal



kills influenza viruses on contact*

inactivates 99.99% of Influenza **H1N1***

pandemic & seasonal strains*

1 MASK

BioFriend™
biomask
universal

- Kills Influenza viruses on contact*
- Inactivates Influenza A & B viruses*
- Pandemic & seasonal strains*
- Easy breathing
- Simple to use
- Comfortable face-design

High Barrier
Surgical Face Mask
Meets ASTM F2100-07 Standard

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated.

INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. It is also intended for use during periods of seasonal influenza or an influenza pandemic.

Meets ASTM F2100-07 High Barrier Class: Synthetic Blood Penetration Resistance - 160 mmHg; Flammability - Class 1; DP < 3.0; Bacterial Filtration Efficiency ≥ 98%; Particle Filtration Efficiency ≥ 98% at 0.1 micron.

Part of an innovative range of products powered by BioFriend™ technology.

Technology by
filligent™
creating global health choices

Website: www.filligent-usa.com
Email: filligent-usa@filligent.com

DISPOSABLE SINGLE USE ONLY

inactivates 99.99% of **H1N1** influenza viruses*

*BioMask™ kills (inactivates) 99.99% of the following viruses within five minutes of contact with the surface of the facemask based on laboratory tests only.

Subtype	Isolate
INFLUENZA A	
H1N1	Pandemic H1N1, A/California/07/09 Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Swine (H1N1), A/Swine/1976/31
H2N2	Human (H2N2), A/2/JAPAN/305/57
H3N2	Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Hong Kong/8/68 Human (H3N2), A/Victoria/3/75
H3N8	Equine (H3N8), A/Equine/2/Miami/63
H5N1	Avian (H5N1), NIBRG-14
H5N2	Duck (H5N2), A/Duck/PA/10218/84
H9N2	Avian (H9N2), Turkey/Wis/68
INFLUENZA B	
B	Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40

WARNINGS / CONTRA-INDICATIONS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- This mask does not contain natural latex.
- For use in medical settings only.
- For adult use only.

Pragmatic • Scientific • Patented

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[8]» *Reviewer Comments*:
The sponsor provided labeling that contained the following deficiencies:

A. The sponsor provided labeling that makes broad claims about the performance of the device against influenza viruses. These claims include but are not limited to: "Inactivation of 99.99% of H1N1 influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of <u>all</u> influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim.
    - The sponsor will be asked to provide labeling that <u>only</u> includes antiviral performance claims on virus strains that demonstrated a 4 log or greater reduction during in-vitro testing.
    - In addition, the sponsor will be asked to provide labeling that clearly states that the in vitro antiviral activity demonstrated was only against single isolates of selected influenza virus strains.

K101128/S001: The sponsor stated that the labeling has been revised to include only virucidal performance claims relating solely to the tested virus strains, and for those that demonstrated the necessary virucidal reduction during *in vitro* testing on 5 minutes contact with the surface of the mask

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Conclusion: This is acceptable.

B. The sponsor provided labeling with the claim: "Kills influenza Viruses on Contact." This claim implies an instantaneous inactivation of influenza which has not been substantiated.
   - The sponsor will be asked to remove the claim: "Kills influenza Viruses on Contact" from all labeling.

K101128/S001: The sponsor removed this claim from labeling.
Conclusion: This is acceptable.

C. The sponsor provided labeling with the claim: "BioMask kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file.
   - The sponsor will be asked to revise the above labeling claim to accurately reflect the performance data.

K101128/S001: The sponsor used revised wording: "Kills (inactivates) 99.99% of the following tested Influenza viruses on 5 minutes contact with the surface of the face mask, as tested in laboratories" in the labeling.
Conclusion: This is acceptable.

D. The sponsor included the Indication for Use (IFU) statement in the labeling. Reviewer comments 6 addresses the IFU related deficiencies.

- The sponsor will be asked to revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiency 6.

K101128/S001: The sponsor submitted an amended IFU that was deficient in several areas.
- The sponsor will be asked to include these corrections in labeling.

Conclusion: This is acceptable.

E. The statement: "HOW IT WORKS: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported by performance data.

- The sponsor will be asked to provide supporting data or revise/remove this claim.

K101128/S001: The sponsor has not provided sufficient data to support this claim.
- The sponsor will be asked to provide supporting data or revise/remove this claim.

K101128/S002: The sponsor provided performance testing that supports this claim and demonstrates that fluid and viruses can be draw to the inner layers of the mask and deactivated by the copper/zinc inner layer.
Conclusion: This is acceptable.

F. The sponsor will be asked to include the following statement: No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from influenza infection."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K101128/S001: The sponsor provided labeling that includes the above statement.
Conclusion: This is acceptable.

G. The sponsor will be asked to address the following issues with the provided labeling:

i. Please add to the Warnings/Contraindications section a Caution that patients with hypersensitivity to citric acid, copper or zinc should not use this device.

K101128/S002: The cautionary statement, "Do not use if hypersensitive to copper or zinc" has been added to the labeling as requested.
Conclusion: This is acceptable.

ii. Please remove all symbols from the labeling of this device unless they are accompanied by the English language explanation of the symbol.

K101128/S002: All symbols on the labeling of the device are now accompanied by English language explanations of the relevant symbols, or have been removed entirely.
Conclusion: This is acceptable.

iii. The "Premium" BioMask should add the Caution that the small "ear adjuster" beads may pose a choking hazard to young children if separated from the device.

K101128/S002: The cautionary statement, "Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately," has been added to the labeling of the Premium BioFriend™ BioMask™ surgical facemask.
Conclusion: This is acceptable.

iv. Please place the word "tested" in normal or larger print in the phrases below (as indicated in red) to clarify to users that only a few (18) strains of influenza have been tested against this mask.

Kills 99.9% of tested Flu Viruses tested *"
"Inactivates 99.99% of tested H1N1 influenza virus tested*"

K101128/S002: The sponsor provided labeling to appropriately address this issue.
Conclusion: This is acceptable.

v. The phrase "Seasonal and pandemic flu strains*including swine flu and bird flu*" appears to be too broad and deciphering the significance of the asterixis is not clear to the reader. This phrase should be revised. Adding "testing" or "tested" at the beginning could be considered.

K101128/S002: The labeling phrase, "seasonal and pandemic flu strains* including swine flu and bird flu*" has been revised to "tested seasonal and pandemic flu strains* including swine flu and bird flu*".
Conclusion: This is acceptable.

vi. "Protective" without further explanation implies a claim for protection against the disease influenza. This should be revised for clarity or deleted.

K101128/S002: "Protective" has been removed from the packaging as requested and amended to "high barrier protection," in reference to the mask being a High Barrier Surgical Face Mask meeting ASTM F2100-07 Standards.
Conclusion: This is acceptable.

vii. "Part of a range of innovative products" is not part of this submission and so should not appear in the labeling for this specific device. This phrase should be deleted.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

K101128/S002: The phrase "Part of a range of innovative products" has been deleted from the device labeling as requested.

viii. The statement "How it works: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported. Please provide supporting data or remove this claim. The sponsor has not provided data to adequately support this claim yet; it should be deleted.

K101128/S002: Appropriate data has been provided to support this claim.
Conclusion: This is acceptable.

ix. The phrase "†when used as intended" is vague and confusing as a free-standing phrase. It should be explained in detail or deleted.

K101128/S002: The phrase "† when used as intended," has been deleted from the labeling as requested.
Conclusion: This is acceptable.

x. The phrase "This mask does not contain natural latex" needs to be revised to say "natural rubber latex" for accuracy.

K101128/S002: The phrase "This mask does not contain natural latex" has been revised to, "This mask does not contain natural rubber latex" as requested.
Conclusion: This is acceptable.

xi. The claim "easy breathing" is a vague, ambiguous claim that could be misinterpreted. This should be removed from the labeling.

K101128/S002: The "easy breathing" claim was removed from the labeling as requested.
Conclusion: This is acceptable.

xii. The sponsor provided labeling in the S002 submission that contained the following labeling concerns:

The following objectionable and misleading phrases remain in the BioMask labeling:

- "kills **99.99%** of FLU VIRUSES tested*"
- "tested **seasonal & pandemic flu strains***"
- "inactivates **99.99%** of **H1N1** influenza virus tested*
- **"Kills (inactivates) 99.99%** of the following tested **influenza viruses** on 5 minutes contact..."
- **"99.99% of influenza viruses"**
- The effect of the bolding and font size used is to imply **"kills 99.99% of flu viruses"** and **"inactivates 99.99% of H1N1" influenza viruses.** Such claims are incorrect. The sponsor should be informed that FDA considers that the sponsor's use of bolding and font size changes to create misleading claims in its labeling. These statements should be revised. The sponsor may either "bold" or increase the font size for "tested" in all of these phrases to make them equivalent to the rest of the text.
- Where the sponsor has "bolded" the phrase **"99.99% of influenza viruses"** in the middle of a long paragraph, it should either remove the "bold" font or replace it with **"99.99% of tested strains of influenza viruses"**.
- On some box panels, the sponsor uses the term "high barrier protection" without the ASTM F2100-07 Standard reference. The sponsor should be asked to either remove the isolated phrase "high barrier protection" or to revise it wherever it is used to remove "protection" and include "meeting ASTM F2100-07 Standard".
- The FDA guidance document on Surgical Masks does not discuss or advise claims based on a perception of "cool" for a Delta-P value of 2 to 3, much less an extrapolation to a claim for "easy breathing". This claim is vague and open to misinterpretation. As previously requested, this claim should be deleted.

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These issues were addressed through interactive review and the sponsor provided amended labeling that appropriately addressed all of the above concerns.
Conclusion: This is acceptable.

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[redacted]

- The sponsor will be asked to please clarify if these claims are intended for the subject of this submission as they have not been supported by data.

K101128/S001: The sponsor stated that the above claims are associated with another product, not the subject of the submission.
Conclusion: This is acceptable.

VII. Sterilization/Shelf Life/Reuse

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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VIII. Biocompatibility
Discussed in Performance Testing – Animal. Refer to Section XI.

IX. Software
N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
N/A

XI. Performance Testing – Bench

(b)(4)

[redacted]

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[redacted]

The conclusions of the above performance tests are acceptable.

Safety/Toxicology

The sponsor was advised, in pre-submission interactions, to provide data on the release of the antimicrobial agents

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[redacted]

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[redacted]

mdl = method detection limit
nd = none detected
* Initial value is from the 1st specimen analyzed; 2nd value is the sum of 4 specimens

The report states that only acetate was detected in the air effluent samples of the first two mask samples but not from the third

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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In Vitro Antimicrobial Performance Data

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HEPES and 1mM EDTA.

Type	Isolate	Initial $Log_{10}TCID_{50}$	Output $Log_{10}TCID_{50}$	Log Reduction

(b)(4)

Assessment of the Virucidal Effectiveness of Copper and Zinc Ions against Influenza

The sponsor performed tests of the anti-influenza activity of aqueous suspensions of copper and zinc. These tested were not included in the review. The material tested is not the final finished product which is the subject of this submission and the test method does not simulate the conditions of use of the BioMask. These results are irrelevant to this submission and cannot serve as adequate evidence for "antiviral" activity for the copper and zinc acetate salts in the second layer of the BioMask.

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[12]» *Reviewer Comments:*

(b)(4)

[redacted]

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[redacted]

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[redacted]

Zinc

Zinc is also a widely dispersed element and it is an essential human nutrient. The sponsor states that there are reports of zinc causing metal fume fever, "however, it is unlikely to occur when zinc concentrations are

(b)(4)

[redacted]

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(b)(4)

[14]» *Reviewer Comments:*

(b)(4)

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log_{10} reduction. However, the laboratory stock culture of this virus was only 6.25 log_{10}. The sponsor therefore decided that the result was "acceptable" (see above) and that the assay would not be repeated.

(b)(4)

[redacted]

cytotoxicity of the mask material itself which the sponsor has estimated as at least a 0.5 log_{10} effect.

	Isolate	Initial Viral Load (Log_{10} $TCID_{50}$)	Average Log Reduction ± 95% CI for Average of 3 replicates Nov. 2010	Average Log Reduction ±95% CI calculated for 3 replicates Apr. 2010

(b)(4)

[redacted]

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[redacted]

Conclusion: This is acceptable.

Note: The Center for Drug Evaluation and Research was contacted regarding the reproducibility of the anti-influenza activity of the outer layer of the mask and the relative contribution to the mask's **achieved anti-influenza activity of the copper and zinc acetate. A consult review was generated by Takashi E. Komatsu, Ph.D. His additional questions were provided below:**

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[redacted]

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[redacted]

Conclusion: This is acceptable.

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standards that demonstrates the sensitivity of the irritation assay.

K101128/S001: The sponsor provided a rationale for not including a positive control to the irritation test that

(b)(4)

[redacted]

Conclusion: This is acceptable.

XIII. Performance Testing – Clinical
N/A

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		√	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		√	If **YES** = Stop **NSE**
3. Same Technological Characteristics?		√	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	√		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		√	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	√		If **NO** = Stop **NSE**
8. Performance Data Available?	√		**If NO = Request Data**
9. Data Demonstrate Equivalence?	√		Final Decision: SE

Note: Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
The IFU of the subject device addresses the antimicrobial performance of the mask against specific Influenza viruses
2. Explain why there is or is not a new effect or safety or effectiveness issue:
Safety and effectiveness can be evaluated by performance testing
3. Describe the new technological characteristics:
Presence of copper acetate, zinc acetate and citric acid in and on mask.
4. Explain how new characteristics could or could not affect safety or effectiveness:
Safety and effectiveness can be evaluated by performance testing
5. Explain how descriptive characteristics are not precise enough:
Performance tested is required to ensure that device is safe, effective and meets performance claims
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

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Performance of the device can be evaluated using traditional mask performance tests and existing methods for evaluating microbial reduction.

7. Explain why accepted scientific methods for analyzing safety and effectiveness do or don't exist.
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The device demonstrated adequate surgical mask performance and provided sufficient evidence to support the antiviral claims.

XV. Deficiencies

All deficiencies are resolved.

[1]» The sponsor provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard.

- The sponsor will be asked to provide a new Standards Data Report for 510(k)s form for this standard that cites conformance to ISO 10993-10:2002 This form can be found at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf

K101128/S001: The sponsor provided an amended Standards Data Report for 510(k)s form that specified the ISO-10993-10:2002 standard.

Conclusion: This is acceptable.

[2]» The sponsor provided a 510(k) summary that did not contain an adequate description of the subject device. The sponsor did not indicate the subject device models or explain the differences between all subject models intended for clearance.

- The sponsor will be asked to provide an amended 510(k) summary that lists the model numbers of all devices intended for clearance in this submission and explains all differences between all device models and predicates. The sponsor will be asked to ensure that the amended 510(k) summary addresses all related deficiencies in this memorandum.

K101128/S001: The sponsor provided a 510(k) summary that identified all device models in the submission and contained a sufficient comparison to the predicate device. However the 510(k) summary contained the following ambiguous statements:

- "Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."
- "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."
- "These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:
  - Replace "biologicals" with "viruses."
  - Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

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- Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested.

The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

K101128/S002: The sponsor provided an amended 510(k) summary. The modifications made by the sponsor appropriately addressed the FDA requests.

The sponsor provided the exact scientific strain identification for Avian Influenza H9N2: Influenza A/Turkey/Wisconsin/1966.

Conclusion: This is acceptable.

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[redacted]

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(b)(4)

[redacted]

Conclusion: This is acceptable.

[6]* The sponsor will be asked to provide data to support the statement that both the viral inoculum and the citric acid on the surface of the mask are actually drawn into the inner layers of the mask during testing and use. The sponsor will be asked to provide the pH achieved in the second layer of the mask during challenge testing.

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[redacted]

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[redacted]

Conclusion: This is acceptable.

[7]»The sponsor provided an Indication for Use (IFU) statement that was deficient in the following areas:

A. The sponsor did not list the model numbers of the subject device. The sponsor should clearly specify all device models and state their respective model numbers.
   - The sponsor will be asked to provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. The sponsor will be asked to include a description of the differing features between model numbers.

K101128/S001: The sponsor provided an IFU statement with an adequate description of all device models.

Conclusion: This is acceptable.

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B. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007.

- The sponsor will be asked to revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

K101128/S001: The sponsor provided an IFU statement that identified all claimed antiviral agents and indicated there intended purposes. However the IFU statement contained the following ambiguous statements:

"Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

"These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:

Replace "biologicals" with "viruses."

Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested. The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

K101128/S002: The sponsor amended the IFU to read:
"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses:...."
This change was reflected in the labeling and 510(k) summary.
The sponsor replaced biologicals with viruses and removed the statement that the devices protect the wearer from the splash and spray of blood and bodily fluids
Conclusion: This is acceptable.

C. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures."

- The sponsor will be asked to revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

K101128/S001: The sponsor provided an IFU statement that replaced removed the language not found in 21 CFR 878.4040 and replaced it with: "They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices

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also help to protect the wearer from splash and spray of blood and body fluids." The last sentence of this statement is addressed in the above deficiency and the other content of this statement is acceptable.

Conclusion: This is acceptable.

D. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only."
   - The sponsor will be asked to remove the above statement from the IFU; it has not been supported by performance testing.

   K101128/S001: The sponsor removed this statement from the IFU.

Conclusion: This is acceptable.

E. The Indication for Use (IFU) statement did not list the influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask.
   - The sponsor will be asked to include the influenza virus strains that have been shown to be adequately reduced (>4log reduction) by the activity of the mask in the IFU statement.

   K101128/S001: The sponsor included the tested viruses on the IFU statement.

Conclusion: This is acceptable.

F. The revised IFU statement should address all listed deficiencies.

K101128/S001: The sponsor has not demonstrated the antiviral performance of the copper acetate and zinc acetate in the final finished subject device.
- The sponsor will be asked to provide performance data using the final finished product that demonstrates the antiviral performance of zinc acetate and copper acetate on the claimed viruses or remove all performance claims of these compounds from the IFU and all device labeling.

K101128/S002: The sponsor provided data that supports the antiviral, performance of zinc and copper on the mask and The IFU statement is now acceptable.

Conclusion: This is acceptable.

[8]» *Reviewer Comments:*

The sponsor provided labeling that contained the following deficiencies:

A. The sponsor provided labeling that makes broad claims about the performance of the device against influenza viruses. These claims include but are not limited to: "Inactivation of 99.99% of H1N1 influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of <u>all</u> influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim.
   - The sponsor will be asked to provide labeling that <u>only</u> includes antiviral performance claims on virus strains that demonstrated a 4 log or greater reduction during in-vitro testing.
   - In addition, the sponsor will be asked to provide labeling that clearly states that the in vitro antiviral activity demonstrated was only against single isolates of selected influenza virus strains.

   K101128/S001: The sponsor stated that the labeling has been revised to include only virucidal performance claims relating solely to the tested virus strains, and for those that demonstrated the necessary virucidal reduction during *in vitro* testing on 5 minutes contact with the surface of the mask

Conclusion: This is acceptable.

B. The sponsor provided labeling with the claim: "Kills influenza Viruses on Contact." This claim implies an instantaneous inactivation of influenza which has not been substantiated.
   - The sponsor will be asked to remove the claim: "Kills influenza Viruses on Contact" from all labeling.

   K101128/S001: The sponsor removed this claim from labeling.

Conclusion: This is acceptable.

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C. The sponsor provided labeling with the claim: "BioMask kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file.

- The sponsor will be asked to revise the above labeling claim to accurately reflect the performance data.

K101128/S001: The sponsor used revised wording: "Kills (inactivates) 99.99% of the following tested Influenza viruses on 5 minutes contact with the surface of the face mask, as tested in laboratories" in the labeling.

Conclusion: This is acceptable.

D. The sponsor included the Indication for Use (IFU) statement in the labeling. Reviewer comments 6 addresses the IFU related deficiencies.

- The sponsor will be asked to revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiency 6.

K101128/S001: The sponsor submitted an amended IFU that was deficient in several areas.

- The sponsor will be asked to include these corrections in labeling.

Conclusion: This is acceptable.

E. The statement: "HOW IT WORKS: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported by performance data.

- The sponsor will be asked to provide supporting data or revise/remove this claim.

K101128/S001: The sponsor has not provided sufficient data to support this claim.

- The sponsor will be asked to provide supporting data or revise/remove this claim.

K101128/S002: The sponsor provided performance testing that supports this claim and demonstrates that fluid and viruses can be draw to the inner layers of the mask and deactivated by the copper/zinc inner layer.

Conclusion: This is acceptable.

F. The sponsor will be asked to include the following statement: No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from influenza infection."

K101128/S001: The sponsor provided labeling that includes the above statement.

Conclusion: This is acceptable.

G. The sponsor will be asked to address the following issues with the provided labeling:

i. Please add to the Warnings/Contraindications section a Caution that patients with hypersensitivity to citric acid, copper or zinc should not use this device.

K101128/S002: The cautionary statement, "Do not use if hypersensitive to copper or zinc" has been added to the labeling as requested.

Conclusion: This is acceptable.

ii. Please remove all symbols from the labeling of this device unless they are accompanied by the English language explanation of the symbol.

K101128/S002: All symbols on the labeling of the device are now accompanied by English language explanations of the relevant symbols, or have been removed entirely.

Conclusion: This is acceptable.

iii. The "Premium" BioMask should add the Caution that the small "ear adjuster" beads may pose a choking hazard to young children if separated from the device.

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K101128/S002: The cautionary statement, "Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately," has been added to the labeling of the Premium BioFriend™ BioMask™ surgical facemask.
Conclusion: This is acceptable.

iv. Please place the word "tested" in normal or larger print in the phrases below (as indicated in red) to clarify to users that only a few (18) strains of influenza have been tested against this mask.

Kills 99.9% of tested Flu Viruses tested *"
"Inactivates 99.99% of tested H1N1 influenza virus tested*"
K101128/S002: The sponsor provided labeling to appropriately address this issue.
Conclusion: This is acceptable.

v. The phrase "Seasonal and pandemic flu strains*including swine flu and bird flu*" appears to be too broad and deciphering the significance of the asterixis is not clear to the reader. This phrase should be revised. Adding "testing" or "tested" at the beginning could be considered.
K101128/S002: The labeling phrase, "seasonal and pandemic flu strains* including swine flu and bird flu*" has been revised to "tested seasonal and pandemic flu strains* including swine flu and bird flu*".
Conclusion: This is acceptable.

vi. "Protective" without further explanation implies a claim for protection against the disease influenza. This should be revised for clarity or deleted.
K101128/S002: "Protective" has been removed from the packaging as requested and amended to "high barrier protection," in reference to the mask being a High Barrier Surgical Face Mask meeting ASTM F2100-07 Standards.
Conclusion: This is acceptable.

vii. "Part of a range of innovative products" is not part of this submission and so should not appear in the labeling for this specific device. This phrase should be deleted.
K101128/S002: The phrase "Part of a range of innovative products" has been deleted from the device labeling as requested.
Conclusion: This is acceptable.

viii. The statement "How it works: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported. Please provide supporting data or remove this claim. The sponsor has not provided data to adequately support this claim yet; it should be deleted.
K101128/S002: Appropriate data has been provided to support this claim.
Conclusion: This is acceptable.

ix. The phrase "†when used as intended" is vague and confusing as a free-standing phrase. It should be explained in detail or deleted.
K101128/S002: The phrase "† when used as intended," has been deleted from the labeling as requested.
Conclusion: This is acceptable.

x. The phrase "This mask does not contain natural latex" needs to be revised to say "natural rubber latex" for accuracy.
K101128/S002: The phrase "This mask does not contain natural latex" has been revised to, "This mask does not contain natural rubber latex" as requested.
Conclusion: This is acceptable.

xi. The claim "easy breathing" is a vague, ambiguous claim that could be misinterpreted. This should be removed from the labeling.

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[redacted]

evaluate the pH of the outer mask layer and would analytically assess the amounts of citric acid, copper and zinc remaining in the BioMask. This is addressed in reviewer's comment 11-C.

Conclusion: This is acceptable.

E. *K101128/S001:* The sponsor will be asked to provide a shelf life test report lists all device properties

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evaluated with the shelf life testing. For each tested property, the sponsor will be asked to provide:

- *The product types to be tested*

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Ingestion of a small amount of citric acid would be unlikely to cause any adverse effects. Citric acid as a food additive is "generally recognized as safe" (GRAS). It is present in many foods, antacid OTC products and oral pharmaceutical preparations. The amount of citric acid extracted from the BioMask at 8 hours is 28.22 mg. The sponsor addressed this concern appropriately.

Conclusion: This is acceptable.

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K101128/S002: The sponsor provided data to address this concern. The data is summarized under reviewer comment 13 in the main body of this memorandum.

Conclusion: This is acceptable.

(b)(4)

[redacted]

The BioMask device brings innate nonspecific effects to an antiviral performance assay which must be accounted for in the design and conduct of the assays. In this case, it is necessary to insure a high enough viral challenge inoculum in each assay in order to be able to accurately observe whether or not the BioMask

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K101128/S002: The sponsor indicated that these viruses would be removed from the IFU, 510(k) summary and labeling.

Conclusion: This is acceptable.

(b)(4)

[redacted]

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Conclusion: This is acceptable.

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 145

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(b)(4)

[redacted]

S002 Deficiencies:

1 – The sponsor provided an Indications-for-Use Statement, 510(k) Summary and labeling that use the term "kill" for viruses. The FDA believed that this term is not acceptable for viruses.

- The sponsor will be asked to provide amended Indications-for-Use Statement, 510(k) Summary and labeling that removes the term "kill" and only uses the term "inactivate".

2 – FDA has released a new product code for the subject device.

- The sponsor will be asked to amend the 510(k) summary by removing the FXX product code and replacing it with OUK.

3 – The sponsor has not provided testing that fully addresses the use conditions of the subject device. The sponsor provided leach-off data with simulated salivary contact, but the antiviral performance of the subject device for extended use with soil and/or saliva on the surface of the mask and repeated viral challenges has not been determined.

- The sponsor will be asked to demonstrate whether the subject device is able to sustain antibacterial effectiveness over a period of time during use of the device. Will this level of performance be maintained over the expected use life of this device, which may be several hours? Since the claimed antiviral agents used in and on the surface of the masks that are the subject of this submission have never been approved by CDER as a drug, FDA has no data on the stability of antiviral performance of these compounds during use. The sponsor will be asked to provide detailed protocol of the evaluation of the subject mask surfaces against repeated challenge with the claimed influenza virus strains. The sponsor will be asked to ensure that the performance addresses performance of the mask with appropriate repeated viral challenges and soil conditions that could be expected during use.

Contact History:

- The sponsor was contacted on April 26, 2010 regarding additional submission material.
- The sponsor replied on April 26, 2010.
- The sponsor was contacted on April 27 with a request for supplemental material.
- The sponsor replied to the request on May 5, 2010.
- A request for additional information was mailed to the firm May 21, 2010.
- A request for additional information was emailed and faxed to the firm December 29, 2010.
- A request for information through interactive review was sent to the sponsor February 22, 2011
- A request for information through interactive review was sent to the sponsor February 25, 2011
- A response to the February 2011 requests for information was provided by the sponsor March 3, 2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 146

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Recommendation:

SE above requested information.
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Mask.
Regulatory Class: Class II
Product Code: OUK

Steven Elliott, MS.
Reviewer

March 4, 2011
Date

Elizabeth Claverie-Williams
Branch Chief

3/4/11
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Date:	March 4, 2011	
To:	The Record	Office: ODE
From:	Steven Elliott Biochemistry/Physiology Reviewer	Division: DAGID
Through:	Elizabeth Claverie-Williams, Branch Chief, INCB	
510(k) Holder:	Filligent HK Limited 7/F 69 Jervois st. Sheung Wan, Hong Kong, HK	
Device Name:	BioFriend BioMask Surgical Face Mask.	
Contact:	Melissa Mowbray-D'Arbela	
Phone:	852-2542-2400	
Fax:	852-2542-2411	
Email:	melissa@filligent.com	

We have completed our review of the supplement to the above referenced 510(k). We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you have provided. To complete the review of this submission, please provide a response to the following questions and/or recommendations.

In order to continue our review of this submission, we request the following:

1]] You provided an Indications-for-Use Statement, 510(k) Summary and labeling that use the term "kill" for viruses. The FDA believed that this term is not acceptable for viruses.
Please provide amended Indications-for-Use Statement, 510(k) Summary and labeling that removes the term "kill" and only uses the term "inactivate".

2]] FDA has released a new product code for the subject device.
Please amend the 510(k) summary by removing the FXX product code and replacing it with OUK.

3]] You have not provided testing that fully addresses the use conditions of the subject device. you provided leach-off data with simulated salivary contact, but the antiviral performance of the subject device for extended use with soil and/or saliva on the surface of the mask and repeated viral challenges has not been determined.
Please demonstrate whether the subject device is able to sustain antibacterial effectiveness over a period of time during use of the device. Will this level of performance be maintained over the expected use life of this device, which may be several hours? Since the claimed antiviral agents used in and on the surface of the masks that are the subject of this submission have never been approved by CDER as a drug, FDA has no data on the stability of antiviral performance of these compounds during use. Please provide detailed protocol of the evaluation of the subject mask surfaces against repeated challenge with the claimed influenza virus strains. Please ensure that the performance addresses performance of the mask with appropriate repeated viral challenges and soil conditions that could be expected during use.

Please provide this information within 30 days. Your document has been placed on hold pending receipt of the above additional information. The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to the Document Mail Center (DMC) at the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Document Mail Center - WO66-0609
Silver Spring, MD 20993-0002

Correspondence sent to any address other than the above address will not be considered as part of your official 510(k) submission. Therefore, please forward the original copies of all correspondence to the DMC so that we may

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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proceed with the review of your submission. To expedite the processing of you review, you may forward an electronic response to the deficiencies directly to me (Steven Elliott at steven.elliott@fda.hhs.gov). We request that you provide detailed item-by-item responses to the attached request for additional information. The suggested format is to restate the question and/ or comment, state your response to the Agency's request/recommendation and reference the location of appropriate supporting documentation in file.

If you have any questions concerning the content of this letter, please contact me by fax at (301) 847-8109, phone at (301)796-5285 or by e-mail at steven.elliott@fda.hhs.gov.

Steven Elliott, B.S. M.S.
Biochemistry/Physiology Reviewer
Infection Control Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Office of Device Evaluation/Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Consultation Review

Document Number: K101128/S002
Device Name: BioFriend BioMask
Sponsor: Filligent HK Limited

Reviewer: Sheila A. Murphey, MD
Medical Officer, INCB
February 25, 2011

Subject

Filligent HK Ltd has submitted their responses to FDA's requests for additional information after the review of the S001 response for K101128 for the BioFriend BioMask (2 models). In this consult, I will review the responses to all of the questions which I had originally provided to the sponsor plus the responses submitted for the CDRH Division of Virology for this consult. I hope that the CDER reviewer will also be able to comment on the responses to his questions. However, the remaining FDA review time is now limited and that may not be possible.

FDA Question 1

In the Indications for Use/Statement of Intended Use statement added to the 510(k) Summary, the phrase "Which form.....on biologicals" is incorrect. Performance testing on this device has examined only influenza viruses. Please replace "biologicals" with "influenza viruses".

Sponsor's Response

The sponsor states that it has replaced "biologicals" with "influenza viruses" in both the Indications for Use statement and the Statement of Intended Use" of the 510(k) Summary. The sponsor has also replaced the word "electrostatic' with "ionic" in the two sections as in "which form ionic bonds with negatively charged" side groups on influenza virus".

Reviewer Comment

This response is satisfactory; this particular deficiency is resolved.

The sponsor should be asked, however, to add the following statement to the Indications for Use statement "Correlation between in vitro testing results and any clinical event has not been tested" both in the free-standing Indication for Use statement and in that section of the 510(k) Summary. This should be placed just after the list of tested influenza strains.

FDA Question 2

In the Indications for Use/Statement of Intended Use statement added to the 510(k) Summary, the phrase "...tests against seasonal, pandemic, avian, swine and equine Influenza viruses including..." is

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misleading because it implies that additional strains of virus have been tested. Please revise this statement to "...tests against these specific Influenza virus strains – Influenza A H1N1 (A/California/07/2009 (2009 pandemic strain), A Brisbane/59/2007..."

Sponsor's Response

The sponsor has revised the wording as requested. The new wording now specifically identifies the specific viral strains tested. Additionally the full scientific name of the "H9N2" strain has been provided. However, the sponsor has deleted 3 influenza strains from its label claims because the antiviral performance performed to data does not consistently show a 4 log reduction and the sponsor has decided to not repeat the testing using a higher titer virus challenge as advised. These deleted claims were for the influenza viruses B/Brisbane/60/2008, A Hong Kong/8/68 and A/Victoria/3/75.

Reviewer Comment

The sponsor has revised its statement of activity against influenza virus as requested. However, the sponsor has also chosen to delete claims against 3 strains of influenza virus for which it could not demonstrate significant 4 $\log_{10}$ reductions during in vitro viral studies. This means that the sponsor has demonstrated adequate in vitro anti-influenza activity against only 15 strains of virus. However, 15 strains remains in vitro activity against more strains of influenza virus than demonstrated by the GSK Actiprotect N95 respirator. This is acceptable.

FDA Question 3
Please provide the exact scientific strain identification for "Avian Influenza H9N2".

Sponsor's Response

The sponsor has identified this H9N2 influenza virus strain as Influenza A/Turkey/Wisconsin/66

Reviewer Comment

This response is satisfactory; this deficiency is resolved.

FDA Question 4
Please remove the sentence "These devices also help to protect the wearer from splash and spray of blood and body fluids" as previously requested. This wording is not included in 21 CFR 878.4040.

Sponsor's Response

The sponsor has removed this phrase as requested from the Indications for Use section of the 510(k) Summary.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Reviewer Comment

This is satisfactory. However, as noted above under Question 1, the sponsor should be asked to provide a revised "Indications for Use" statement with the requested change made to it and to the 510(k) Summary as noted under Question 1.

FDA Question 5

(b)(4)

[redacted]

FDA Question 6

The submitted studies of the antiviral activity of single layers of the BioMask are compromised by the following scientific issues – pooling of challenge inoculum below the mask resulting in undercounting of the challenge survivor population, nonspecific cytotoxicity of copper and zinc and a very low viral challenge level. In addition and most importantly, studies of the performance of the BioMask should be performed on the complete finished product with all 4 layers. In order to establish whether or not the

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

FDA Question 7

- *Please amend your Indication for Use statement to include the following corrections:*
- *"Which form.....on biologicals" is incorrect. Performance testing on this device has examined only influenza viruses. Please replace "biologicals" with "influenza viruses"*
- *The phrase "...tests against seasonal, pandemic, avian, swine and equine Influenza viruses including..." is misleading because it implies that additional strains of virus have been tested. Please revise this statement to "...tests against these specific Influenza virus strains – Influenza A H1N1 (A/California/07/2009 (2009 pandemic strain), A Brisbane/59/2007..."*
- *Please provide the exact scientific strain identification for "Avian Influenza H9N2"*
- *Please remove the sentence "These devices also help to protect the wearer from splash and spray of blood and body fluids" as previously requested. This wording is not included in 21 CFR 878.4040*
- *You have not yet demonstrated adequate antiviral performance of the copper acetate and zinc acetate in the final finished subject device. Please provide performance data using the final finished product that demonstrates the antiviral performance of zinc acetate and copper acetate on the claimed viruses.*

Sponsor's Response

The sponsor has already responded on these points under FDA Questions 1 through 6.

Reviewer Comment

As noted, the sponsor has already responded to these questions under # 1-6 above. See my comments on those responses. These deficiencies are resolved.

As noted in Question 1, however, one new phrase should be added to both the Indications for Use statement and the 510(k) Summary.

FDA Question 8

In the device labeling, you have used a much smaller font size to indicate that the mask kills 99.99% of tested flu viruses. This may be misleading. Please place the word "tested" in normal or larger print in the phrases below (as indicated in red) to clarify to users that only a few (18) strains of influenza have been tested against this mask.

*"Kills 99.9% of tested Flu Viruses tested *"*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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"Inactivates 99.99% of tested H1N1 influenza virus **tested***"

Sponsor's Response

The sponsor states that it has complied. However, although it has increased the font size used for "tested", it has negated the effect of the font change by using highlighting and bolding on the preceding words.

Reviewer Comment

The following objectionable and misleading phrases remain in the BioMask labeling:

"kills 99.99% of FLU VIRUSES tested"*

"tested seasonal & pandemic flu strains"*

*"inactivates 99.99% of H1N1 influenza virus tested**

"Kills (inactivates) 99.99% of the following tested influenza viruses on 5 minutes contact..."

"99.99% of influenza viruses"

The effect of the bolding and font size used is to imply "kills 99.99% of flu viruses" and "inactivates 99.99% of H1N1" influenza viruses. The sponsor should be informed that FDA considers that the sponsor's use of bolding and font size changes to still be misleading. They must be revised. The sponsor may either "bold" or increase the font size for "tested" in all of these phrases to make it equivalent to the rest of the text.

Where the sponsor has "bolded" the phrase "99.99% of influenza viruses" in the middle of a long paragraph, it must either remove the "bold" font or replace it with "99.99% of tested strains of influenza viruses".

FDA Question 9

*In the revised device labeling, the phrase "Seasonal and pandemic flu strains*including swine flu and bird flu*" appears to be too broad and deciphering the significance of the asterisks may be difficult for the reader. This phrase should be revised since, as presently written, it does not clearly state that the BioMask has been tested only against certain influenza strains. Adding "testing" or "tested" at the beginning could be considered.*

Sponsor's Response

The sponsor states that it has replaced the offending phrase with "tested seasonal and pandemic flu strains including swine flu and bird flu".

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Reviewer Comment

The sponsor has done as requested. However, as noted under Question 8, it has subverted the change mad by its use of font size and bold font. While this particular question has been answered, the revisions noted above under #8 are still needed.

FDA Question 10
"Protective" without further explanation implies a claim for protection against the disease influenza. This should be revised to make it very clear that no clinical benefit from the use of this device has been demonstrated.

Sponsor's Response

The sponsor states that it has removed the term "protective" and replaced it with "High Barrier Surgical Face Mask meeting ASTM F2100-07 Standards".

Reviewer Comment

This revision is suitable as stated. However, on some box panels, the sponsor uses "high barrier protection" without the ASTM Standard reference. The sponsor should be asked to either remove the isolated phrase "high barrier protection" or to revise it wherever used to remove "protection" and include "meeting ASTM F2100-07 Standard".

FDA Question 11
"Part of a range of innovative products" is not part of this submission which reviewed only a single device and so should not appear in the labeling for this specific device. Please delete this phrase.

Sponsor's Response

The sponsor states that it has deleted this phrase from the device labeling.

Reviewer Comment

This response is acceptable; this deficiency is resolved.

FDA Question 12
The label statement "How it works: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are

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inactivated" has not yet been supported. It is not clear how many viable influenza viruses reach the 2nd layer to be killed there. Please provide supporting data or remove this claim.

Sponsor's Response

The sponsor has revised this description to: "How it works: the BioMask has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the outer surface of the mask. The first and second layers of the mask are treated with different compounds that inactivate influenza viruses". The sponsor points out that it had provided the requested scientific supporting data under the response to question 6, which is correct.

Reviewer Comment

The revised wording is acceptable. The scientific proof for the underlying claim has been provided – see the analysis under #6. This deficiency is resolved.

FDA Question 13
The phrase "†when used as intended" is vague and confusing as a free-standing phrase. Please explain this instruction in detail or delete it.

Sponsor's Response

The sponsor has deleted this phrase as requested.

Reviewer Comment

This response is acceptable; this deficiency is resolved.

FDA Question 14
The phrase "This mask does not contain natural latex" should be revised to say "natural rubber latex" for accuracy.

Sponsor's Response
The sponsor has revised the labeling to state "This mask does not contain natural rubber latex".

Reviewer Comment

This revision is acceptable; this deficiency is resolved.

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FDA Question 15
Please add a Caution to the device labeling which advises persons with hypersensitivity to copper or zinc to avoid the use of this device.

Sponsor's Response

The sponsor has added the Warning "Do not use if hypersensitive to copper and zinc" to the labeling.

Reviewer Comment

This response is acceptable; this deficiency is resolved.

FDA Question 16
Please remove all symbols from the labeling of this device unless they are accompanied by the English language explanation of the symbol.

Sponsor's Response

The sponsor states that it has removed from the device labeling any symbols which lack a text explanation. This has been done.

Reviewer Comment

This response is acceptable; this deficiency is resolved.

FDA Question 17
The "Premium" BioMask should add the Caution that the small "ear adjuster" beads may pose a choking hazard to young children if separated from the device. This device should be kept away from children and discarded in a manner which keeps it away from them.

Sponsor's Response

The sponsor has added the Warning "Ear Adjuster may pose a choking hazard to young children if separated from the device. Keep away from young children, discard appropriately" has been added to the labeling of the "Premium" BioMask.

Reviewer Comment

This response is acceptable; this deficiency is resolved.

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FDA Question 18

The labeling contains an "easy breathing" claim. This claim is vague and could be misinterpreted. Please remove the "easy breathing" claim from the device labeling.

Sponsor's Response

The sponsor responds that the BioMask demonstrates a pressure drop (Delta-P) of 2.6 mm H_2O/cm^2 on testing as recommended by FDA. The sponsor reproduces the "Comfort Scale" rating of the differential pressure drop from the "Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions". On that comfort scale, the BioMask Delta-P value would correlate with a user perception of "cool".

Reviewer Comment

The FDA Guidance document does not discuss even claims based on a perception of "cool" for a Delta-P value of 2 to 3, much less an extrapolation to "easy breathing". As noted above, this claim is vague and open to misinterpretation. As previously requested, this claim should be deleted.

(b)(4)

[redacted]

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(b)(4)

[redacted]

Reviewer Comment

The shelf life protocol as described is acceptable. To date, however, FDA has only seen shelf life

(b)(4)

[redacted]

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Sponsor's Response

(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

FDA Question 25

Please discuss what could happen if a small amount of citric acid-containing fluid from the mask were to be inhaled or aspirated into the respiratory tract or swallowed by a wearer of the device, especially a

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wearer with underlying bronchoconstricting disease after the person had been wearing the device for a while.

(b)(4)

[redacted]

FDA Question 26

This question on biocompatibility is from the primary document reviewer. He will review this response.

(b)(4)

[redacted]

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Reviewer Comment

(b)(4)

[redacted]

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(b)(4)

[redacted]

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FDA Question 29

(b)(4)

[redacted]

FDA Question 30

Please provide therapeutic indices for each influenza type/subtype

Sponsor's Response

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Sponsor's Response

(b)(4)

[redacted]

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(b)(4)

[redacted]

In Summary

1. Labeling deficiencies remain and have already been sent to the sponsor for review.

2. The major performance issues appear to have been resolved.

3. The shelf life testing protocol is incomplete and the 12 month test data is not included in this submission (which is unfortunate; the labeling cleared must reflect the 6 month shelf life). This protocol needs to be updated.

Preliminary Deficiencies to be conveyed to the sponsor urgently for resolution prior to final file decision – sent to the primary reviewer on 2/22/2011

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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may either "bold" or increase the font size for "tested" in all of these phrases to make it equivalent to the rest of the text.

Where the sponsor has "bolded" the phrase "**99.99% of influenza viruses**" in the middle of a long paragraph, it must either remove the "bold" font or replace it with "**99.99% of tested strains of influenza viruses**".

3. On some box panels, the sponsor uses "high barrier protection" without the ASTM Standard reference. The sponsor should be asked to either remove the isolated phrase "high barrier protection" or to revise it wherever it is used to remove "protection" and include "meeting ASTM F2100-07 Standard".

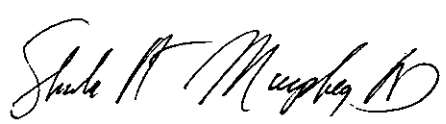
4. The FDA guidance document on Surgical Masks does not discuss or advise claims based on a perception of "cool" for a Delta-P value of 2 to 3, much less an extrapolation to a claim for "easy breathing". This claim is vague and open to misinterpretation. As previously requested, this claim should be deleted.

Second Set of Deficiencies to be Conveyed to the Sponsor - 2/25/11

1. In May of 2010, FDA asked that you provide a report determining the actual levels of the antiviral agents through the shelf life of your device (FDA Question 24, May, 2010. In November, 2010, you responded that you planned to perform that testing at the 12 month real time shelf life testing. However, this planned testing does not appear in the shelf life testing protocol which you have submitted to FDA in response to our December, 2010 Question 22. Please provide a corrected complete shelf life testing protocol which includes all of the stability and performance testing planned for the ongoing, real time evaluation of the BioMask, including the evaluation of the pH of the outer mask layer and the quantitative analyses of citric acid, copper and zinc and the test schedule intervals for these.

2. Please add the current expiration date for your devices to all of the device labeling. Since only the 6 month real time test data is currently available, that is what should appear of the device labeling now.

I will "sign out" this consult today. However, I will also review Dr. Komatsu's comments when they become available and will comment on them if necessary.



Sheila A. Murphey, MD
Medical Officer, INCB
February 25, 2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Addendum to Consultation Review – March 2, 2011

The sponsor has just provided electronically responses to the few remaining deficiencies – labeling and the revision of the shelf life testing protocol. I will review and comment on this material.

1. Please add to the Indications for Use statement and the 510(k) Summary the statement "Correlation between in vitro testing results and any clinical event has not been tested".

Reviewer Comment

The sponsor has complied with this request; this deficiency is resolved.

2. Labeling claims – FDA requested that issues with text size and use of "bold" characters in text be corrected. FDA also asked that "high barrier protection" be used only in conjunction with a reference to ASTM F2100-07 and that "easy breathing" be removed from the device labeling.

Reviewer Comment

The sponsor has complied with this request in all components; this deficiency is resolved.

3. Shelf Life – The sponsor was asked to provide a revised shelf life testing protocol which included periodic testing of the actual levels of the antiviral agents in the BioMask. The sponsor had informed FDA in November, 2010 that such testing was planned. The sponsor was also advised to add the 6 month expiration date for the device to the device labeling at this time, since 12 month data is not yet available.

The sponsor has provided the revised shelf life testing protocol as requested. It includes the quantitative evaluation of the levels of citric acid, copper acetate and zinc acetate and measurement of the pH of the outer surface of the BioMask. It also includes the acceptance criteria for each study. The protocol for the antiviral performance testing is also included.

Reviewer Comment

The sponsor has fully complied with this request; this deficiency is resolved.

In Summary

All of the remaining deficiencies have been resolved. This device appears to be substantially equivalent to its predicate and can be cleared for marketing.

Sheila A. Murphey, MD March 2, 2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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moderate irritation responses when tested with SLS. The primary irritation index scores were 2.6, 2.6 and 2.3.
The testing was indicated to have been performed in August 2010.
The sponsor has demonstrated the ability of the test method to identify potential irritants.
Conclusion: This is acceptable.

All deficiencies are resolved.

Contact History:

- The sponsor was contacted on April 26, 2010 regarding additional submission material.
- The sponsor replied on April 26, 2010.
- The sponsor was contacted on April 27 with a request for supplemental material.
- The sponsor replied to the request on May 5, 2010.
- A request for additional information was mailed to the firm May 21, 2010.
- A request for additional information was emailed and faxed to the firm December 29, 2010.
- A request for information through interactive review was sent to the sponsor February 22, 2011
- A request for information through interactive review was sent to the sponsor February 25, 2011
- A response to the February 2011 requests for information was provided by the sponsor March 3, 2011

Recommendation:

SE above requested information.
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Mask.
Regulatory Class: Class II
Product Code: OUK

Steven Elliott, MS.		March 3, 2011
Reviewer		Date

Elizabeth Claverie-Williams		
Branch Chief		Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 172

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COVER SHEET MEMORANDUM

From: Reviewer Name — Steven Elliott

Subject: 510(k) Number — K101128 / S2

To: The Room

Decision Code: ~~SE~~ TH

Refused to accept (Note: this is considered the first review cycle. See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5611/Screening%20Checklist%207%202%2007.doc)

Hold (Additional Information or Telephone Hold)

✓ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary/510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N/A, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group; different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

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Transcutaneous Adjacent Strain [illegible] 21 No special considerations compared to adult [illegible] years

Nanotechnology

Is this device subject to the Tracking Regulation (Medical Device Tracking [illegible] Guidance, http://www.fda.gov/cdrhcomm/guidance/169.html)

Regulation Number	Class*	Product Code
878.4040	II	OUK

(If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Elizabeth F. Claus-Walls INCB 3/4/11
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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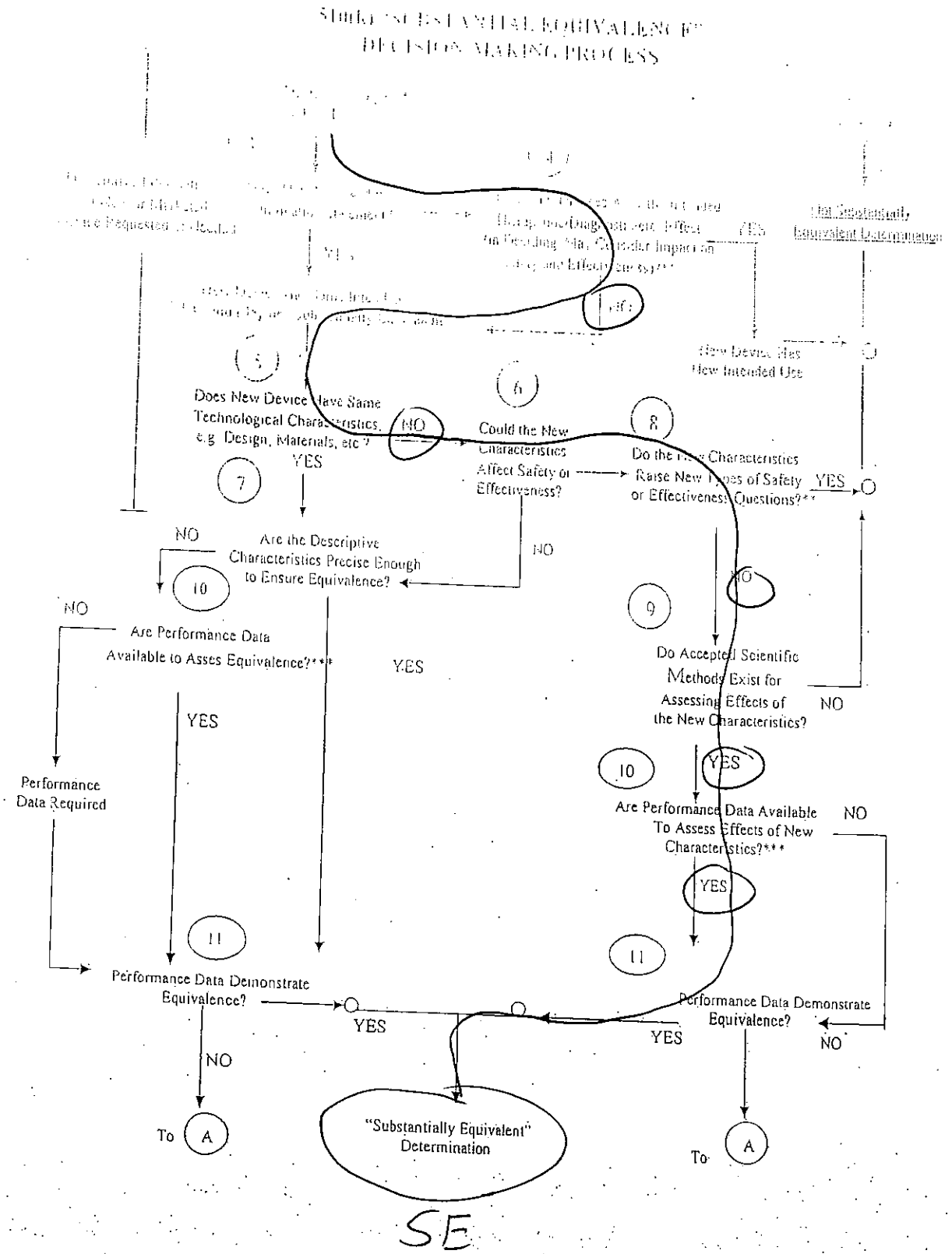

❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Steven Elliott

Subject: 510(k) Number K101128 | S1

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Rev. 7/2/07

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number	Class*	Product Code
878.4040	II	FXX

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Elaine S. Marshall for Elizabeth Claverie-Williams (Branch Chief) INCB (Branch Code) 12/29/10 (Date)

Final Review: _____ (Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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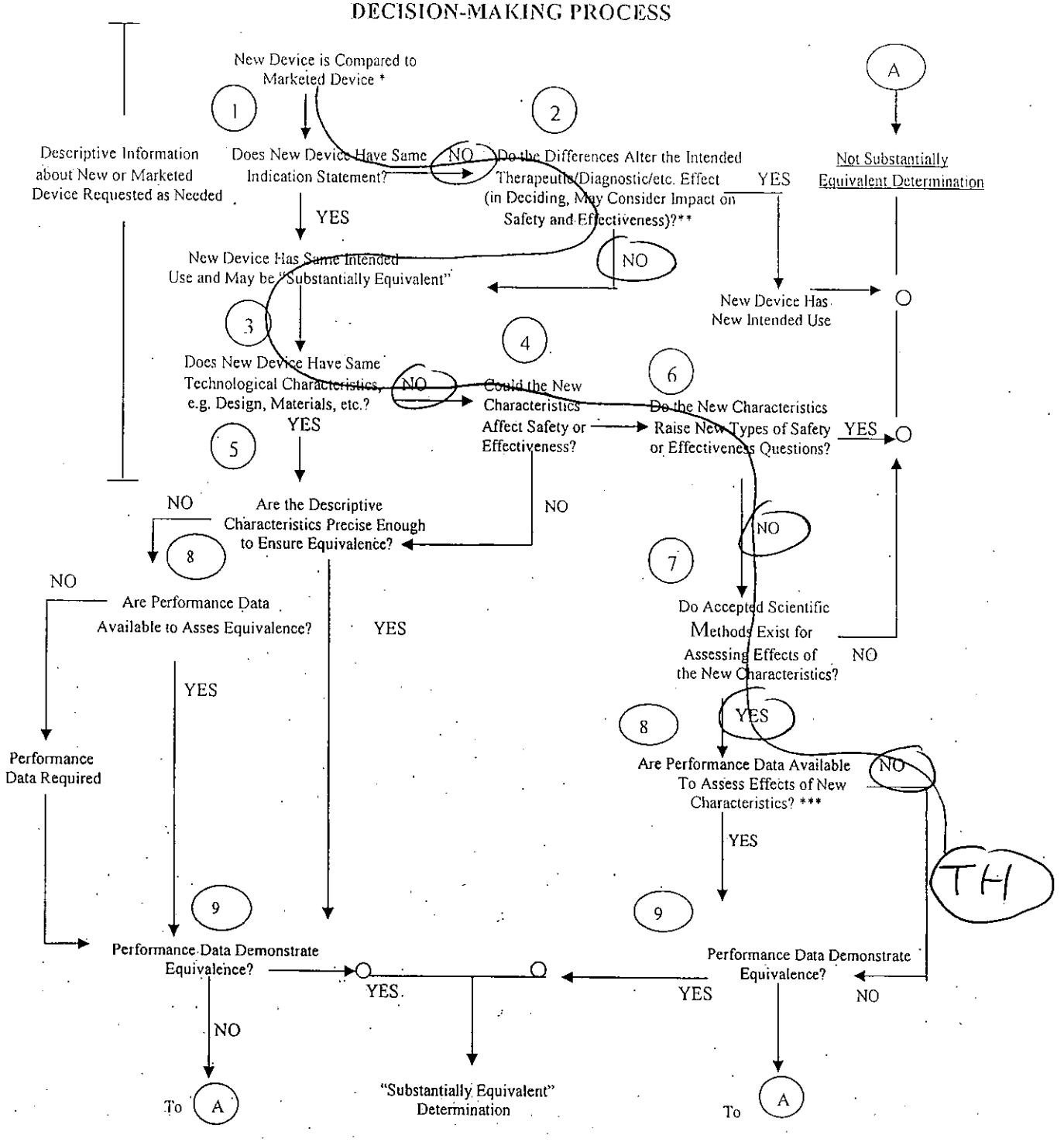
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center -- WO66-G609
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Abbreviated

K101128/S001

Date: December 29, 2010
To: The Record
From: Steven Elliott Biochemistry/Physiology Reviewer
Through: Elizabeth Claverie-Williams, Branch Chief, INCB
510(k) Holder: Filligent HK Limited
7/F 69 Jervois st. Sheung Wan, Hong Kong, HK
Device Name: BioFriend BioMask Surgical Face Mask.
Contact: Melissa Mowbray-D'Arbela
Phone: 852-2542-2400
Fax: 852-2542-2411
Email: melissa@filligent.com

Office: ODE
Division: DAGID

I. Purpose and Submission Summary

Filligent HK Limited would like to introduce the "BioFriend BioMask Surgical Face Mask." into interstate commerce. The firm has submitted a pre-market notification (PMN) [510(K)] for the device.

The firm claims that the "BioFriend BioMask Surgical Face Mask" is a Class II surgical face mask (21 CFR 878.4040), product code FXX).

The information provided in the initial submission was insufficient to determine if the subject device was substantially equivalent to the predicate and the submission was placed on hold. The sponsor has submitted an S001 response. The new information is addressed in the Section marked Deficiencies.

The questions to the sponsor are included at the conclusion of this document.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page OTC	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Data Report Form – Form 3654		√	

Medical Device Standards Referenced:

1. ASTM F2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks.
2. ASTM F2101: 2007 Standard Test method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask materials Using a Biological Aerosol of Staphylococcus aureus.
3. ASTM F2299: 2003 Standard Test method for determining the initial efficiency of materials used in Medical Face Masks to Penetration by Particles Using Latex Spheres.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 180

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4. ASTM F1862: 2007 Standard Test Method for Resistance of Medical Facemasks to Penetration by Synthetic Blood. (Horizontal Projection of Fixed Volume at a Known Velocity)
5. MIL-M-36954C Military Specification, Surgical Mask, Disposable.
6. ISO 10993-10E:2002 Biological Evaluation of Medical Devices— Part 10 Tests for irritation and delayed-type hypersensitivity. – Listed as 2003 in the Standards Data Report for 510(k)s.
7. ISO 10993-18 Biological Evaluation of Medical Devices— Part 18 Chemical characterization of materials.
8. ASTM E1052-96 Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension.

[1]» *Reviewer Comments:*
The sponsor provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard.

- The sponsor will be asked to provide a new Standards Data Report for 510(k)s form for this standard that cites conformance to ISO 10993-10:2002 This form can be found at: **http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf**

K101128/S001: The sponsor provided an amended Standards Data Report for 510(k)s form that specified the ISO-10993-10:2002 standard.
Conclusion: This is acceptable.

The firm has provided its 510(k) Summary in section 5 of the submission:

			YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)					
	Clearly labeled "510(k) Summary"		√		
	Submitter' s name, address, phone #, a contact person		√		
	Date the summary was prepared		√		
	The name of the device/trade name/common name/classification name		√		
	An identification of the legally marketed Predicate		√		
	Description of the subject device			√	
	Statement of intended use (identical to indications for use)		√		
	Technological characteristics	if same, a summary of comparison of technological characters		√	
		If different, a summary of how do they compare to the Predicate		√	
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	√		
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination			√
		Conclusion that data demonstrate SE	√		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 181

	YES	NO	N/A
Required Elements for 510(k) Statement (21 CFR 807.93)			
Signed verbatim statement			

[2]» *Reviewer Comments:*
The sponsor provided a 510(k) summary that did not contain an adequate description of the subject device. The sponsor did not indicate the subject device models or explain the differences between all subject models intended for clearance.

- The sponsor will be asked to provide an amended 510(k) summary that lists the model numbers of all devices intended for clearance in this submission and explains all differences between all device models and predicates. The sponsor will be asked to ensure that the amended 510(k) summary addresses all related deficiencies in this memorandum.

K101128/S001: The sponsor provided a 510(k) summary that identified all device models in the submission and contained a sufficient comparison to the predicate device. However the 510(k) summary contained the following ambiguous statements:

"Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including - Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

"These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:

Replace "biologicals" with "viruses."

Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested. The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

Conclusion: This is not acceptable.

III. Device Description

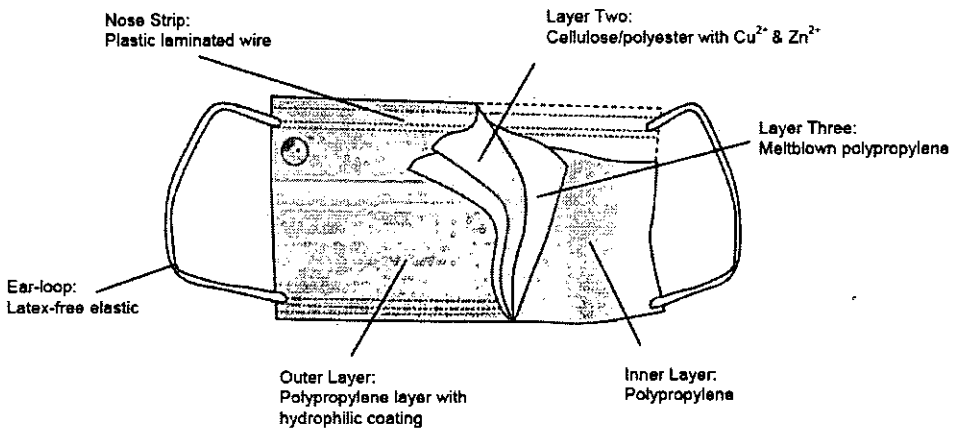
	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 182

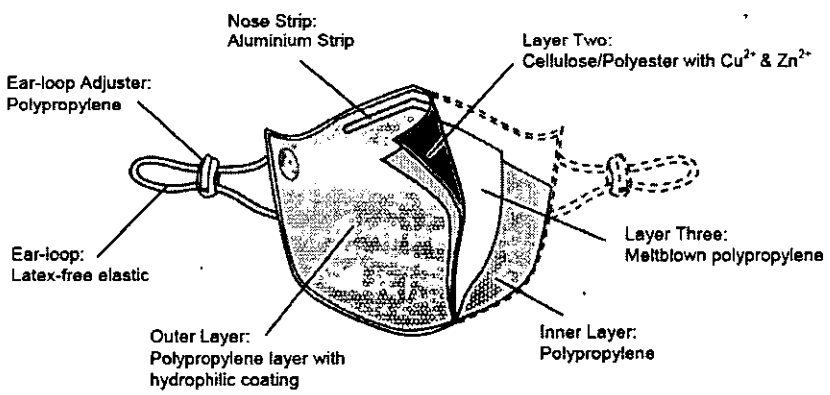
	Yes	No	N/A
Does the device design use software?		√	
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		√	

The sponsor provided the following description:
Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. The outer layer is coated with a hydrophilic plastic. The second layer is treated with copper and zinc. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip. One model is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard "comfort" features such ear adjusters and an anti-fog nose insert.

Universal BF-200-2001:



Premium BF-200-3013



Mode of Action:
The sponsor has indicated the masks to have antimicrobial properties that operated using the following modes of action:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 183

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 184

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 185

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 186

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 187

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Device Name:
BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001 and Premium BF-200-3013

Indications for Use:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as during dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

The sponsor indicated over-the-counter use.

[7]»*Reviewer's Comments:*
The sponsor provided an Indication for Use (IFU) statement that was deficient in the following areas:

A. The sponsor did not list the model numbers of the subject device. The sponsor should clearly specify all device models and state their respective model numbers.
   - The sponsor will be asked to provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. The sponsor will be asked to include a description of the differing features between model numbers.

K101128/S001: The sponsor provided an IFU statement with an adequate description of all device models.
Conclusion: This is acceptable.

B. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007.
   - The sponsor will be asked to revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

K101128/S001: The sponsor provided an IFU statement that identified all claimed antiviral agents and indicated there intended purposes. However the IFU statement contained the following ambiguous statements:

"Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including - Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

"These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:

Replace "biologicals" with "viruses."

Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested. The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

Conclusion: This is not acceptable.

C. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures."
   - The sponsor will be asked to revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

K101128/S001: The sponsor provided an IFU statement that replaced removed the language not found in 21 CFR 878.4040 and replaced it with: "They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and body fluids." The last sentence of this statement is addressed in the above deficiency and the other content of this statement is acceptable.

Conclusion: This is acceptable.

D. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only."
   - The sponsor will be asked to remove the above statement from the IFU; it has not been supported by performance testing.

K101128/S001: The sponsor removed this statement from the IFU.

Conclusion: This is acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 189

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E. The Indication for Use (IFU) statement did not list the influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask.
   - The sponsor will be asked to include the influenza virus strains that have been shown to be adequately reduced (>4log reduction) by the activity of the mask in the IFU statement.

K101128/S001: The sponsor included the tested viruses on the IFU statement.
Conclusion: This is acceptable.

F. The revised IFU statement should address all listed deficiencies.

K101128/S001: The sponsor has not demonstrated the antiviral performance of the copper acetate and zinc acetate in the final finished subject device.
- The sponsor will be asked to provide performance data using the final finished product that demonstrates the antiviral performance of zinc acetate and copper acetate on the claimed viruses or remove all performance claims of these compounds from the IFU and all device labeling.

Conclusion: This is not acceptable.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 190

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

VI. Labeling

The sponsor provided the package labeling (individual package and box) for both mask models. Samples of the labeling are included below:

The sponsor included the following instructions on the labeling:

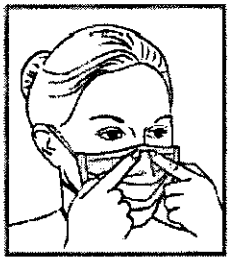
FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask

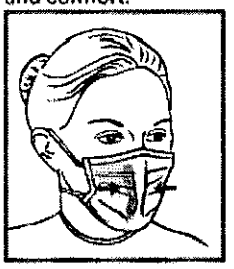
1 Pull loops around ears.

2 Expand mask over nose and under chin.

3 Press forefingers down on both sides of nose.



4 Check for snug fit and comfort.



Replace if damaged or soiled with blood or other bodily fluids.

The following labeling was found as an online brochure:
http://www.filligent.com/uploads/file/BioFriend%20Brochure%20-%20July%2009%20-%20English.pdf

BIOMASK

BioFriend's revolutionary, patented technology traps and kills bacteria and viruses on contact AND allows you to breathe normally:

- Traps and kills 99.9% of harmful germs
- Superior breathability & comfort
- Self-sanitizing for ALL-DAY WEAR
- Reduces cross-contamination of hands and surfaces
- Standard and small sizes

***Kills germs including those that cause Influenza A, Swine Flu, Bird Flu, common colds, measles, MRSA, pneumonia and SARS.**

BioFriend™ traps microbes by mimicking the sites on human cells to which they normally attach, then, destroys them by disrupting their surfaces (viruses) or cell walls (bacteria).

Replace after 12 hours of active wear or earlier, if damaged or soiled with blood or bodily fluids.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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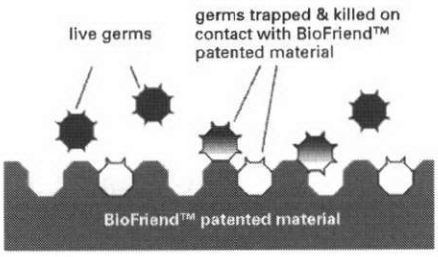
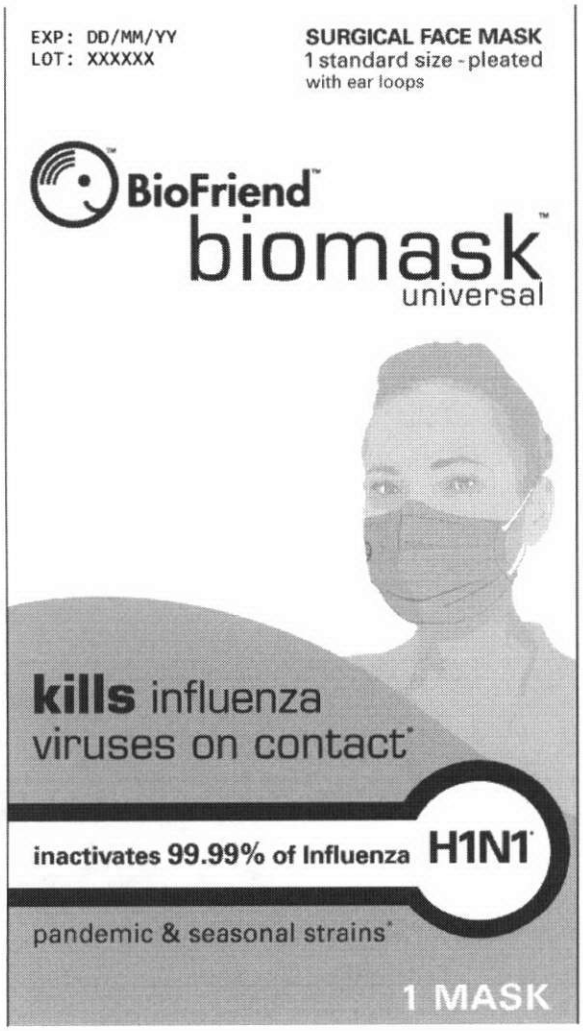


Single Use Package Labeling:



[8]» *Reviewer Comments*:

The sponsor provided labeling that contained the following deficiencies:

A. The sponsor provided labeling that makes broad claims about the performance of the device against influenza viruses. These claims include but are not limited to: "Inactivation of 99.99% of H1N1 influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of <u>all</u> influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim.

- The sponsor will be asked to provide labeling that <u>only</u> includes antiviral performance claims on virus strains that demonstrated a 4 log or greater reduction during in-vitro testing.

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- In addition, the sponsor will be asked to provide labeling that clearly states that the in vitro antiviral activity demonstrated was only against single isolates of selected influenza virus strains.

K101128/S001: The sponsor stated that the labeling has been revised to include only virucidal performance claims relating solely to the tested virus strains, and for those that demonstrated the necessary virucidal reduction during *in vitro* testing on 5 minutes contact with the surface of the mask
Conclusion: This is acceptable.

B. The sponsor provided labeling with the claim: "Kills influenza Viruses on Contact." This claim implies an instantaneous inactivation of influenza which has not been substantiated.
   - The sponsor will be asked to remove the claim: "Kills influenza Viruses on Contact" from all labeling.

K101128/S001: The sponsor removed this claim from labeling.
Conclusion: This is acceptable.

C. The sponsor provided labeling with the claim: "BioMask kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file.
   - The sponsor will be asked to revise the above labeling claim to accurately reflect the performance data.

K101128/S001: The sponsor used revised wording: "Kills (inactivates) 99.99% of the following tested Influenza viruses on 5 minutes contact with the surface of the face mask, as tested in laboratories" in the labeling.
Conclusion: This is acceptable.

D. The sponsor included the Indication for Use (IFU) statement in the labeling. Reviewer comments 6 addresses the IFU related deficiencies.
- The sponsor will be asked to revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiency 6.

K101128/S001: The sponsor submitted an amended IFU that was deficient in several areas.
- The sponsor will be asked to include these corrections in labeling.

Conclusion: This is not acceptable.

E. The statement: "HOW IT WORKS: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported by performance data.
- The sponsor will be asked to provide supporting data or revise/remove this claim.

K101128/S001: The sponsor has not provided sufficient data to support this claim.
- The sponsor will be asked to provide supporting data or revise/remove this claim.

Conclusion: This is not acceptable.

F. The sponsor will be asked to include the following statement: No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from influenza infection."

K101128/S001: The sponsor provided labeling that include the above statement.
Conclusion: This is acceptable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

G. The sponsor will be asked to address the following issues with the provided labeling:

1. Please add to the Warnings/Contraindications section a Caution that patients with hypersensitivity to citric acid, copper or zinc should not use this device.

2. Please remove all symbols from the labeling of this device unless they are accompanied by the English language explanation of the symbol.

3. The "Premium" BioMask should add the Caution that the small "ear adjuster" beads may pose a choking hazard to young children if separated from the device.

4. Please place the word "tested" in normal or larger print in the phrases below (as indicated in red) to clarify to users that only a few (18) strains of influenza have been tested against this mask.

Kills 99.9% of tested Flu Viruses tested *"
"Inactivates 99.99% of tested H1N1 influenza virus tested*"

5. The phrase "Seasonal and pandemic flu strains*including swine flu and bird flu*" appears to be too broad and deciphering the significance of the asterixis is not clear to the reader. This phrase should be revised. Adding "testing" or "tested" at the beginning could be considered.

6. "Protective" without further explanation implies a claim for protection against the disease influenza. This should be revised for clarity or deleted.

7. "Part of a range of innovative products" is not part of this submission and so should not appear in the labeling for this specific device. This phrase should be deleted.

8. The statement "How it works: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported. Please provide supporting data or remove this claim. The sponsor has not provided data to adequately support this claim yet; it should be deleted.

9. The phrase "†when used as intended" is vague and confusing as a free-standing phrase. It should be explained in detail or deleted.

10. The phrase "This mask does not contain natural latex" needs to be revised to say "natural rubber latex" for accuracy.

11. The claim "easy breathing" is a vague, ambiguous claim that could be misinterpreted. This should be removed from the labeling.

Conclusion: This is not acceptable.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 195

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***Kills germs including those that cause Influenza A, Swine Flu, Bird Flu, common colds, measles, MRSA, pneumonia and SARS.**
BioFriend™ traps microbes by mimicking the sites on human cells to which they normally attach, then, destroys them by disrupting their surfaces (viruses) or cell walls (bacteria).

- The sponsor will be asked to please clarify if these claims are intended for the subject of this submission as they have not been supported by data.

K101128/S001: The sponsor stated that the above claims are associated with another product, not the subject of the submission.
Conclusion: This is acceptable.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

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(b)(4)

[redacted]

VIII. Biocompatibility
Discussed in Performance Testing – Animal. Refer to Section XI.

IX. Software
N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
N/A

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 198

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 199

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 260

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[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 201

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 202

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[redacted]

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[redacted]

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[redacted]

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[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

XIII. Performance Testing – Clinical
N/A

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		√	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		√	If **YES** = Stop **NSE**
3. Same Technological Characteristics?		√	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	√		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		√	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	√		If **NO** = Stop **NSE**
8. Performance Data Available?		√	**If NO = Request Data**
9. Data Demonstrate Equivalence?			Final Decision: TH

Note: Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain what performance data is needed:
8. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies
In order to continue our review of this submission, we request the following:
[1]» *Reviewer Comments:*
The sponsor provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

- The sponsor will be asked to provide a new Standards Data Report for 510(k)s form for this standard that cites conformance to ISO 10993-10:2002 This form can be found at: **http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf**

K101128/S001: The sponsor provided an amended Standards Data Report for 510(k)s form that specified the ISO-10993-10:2002 standard.
Conclusion: This is acceptable.

[2]» *Reviewer Comments:*
The sponsor provided a 510(k) summary that did not contain an adequate description of the subject device. The sponsor did not indicate the subject device models or explain the differences between all subject models intended for clearance.

- The sponsor will be asked to provide an amended 510(k) summary that lists the model numbers of all devices intended for clearance in this submission and explains all differences between all device models and predicates. The sponsor will be asked to ensure that the amended 510(k) summary addresses all related deficiencies in this memorandum.

K101128/S001: The sponsor provided a 510(k) summary that identified all device models in the submission and contained a sufficient comparison to the predicate device. However the 510(k) summary contained the following ambiguous statements:

"Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including - Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

"These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:
  Replace "biologicals" with "viruses."

  Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

  Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested. The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

Conclusion: This is not acceptable.

[3]» *Reviewer Comments:*
The sponsor has stated that Citric acid lowers the pH of its environment, but did not indicate the pH on the exterior surface of the mask, or the pH required for the claimed deactivation of specific influenza strains. This information is required to effectively determine the antimicrobial effect of Citric Acid on the

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(b)(4)

[redacted]

Conclusion: This is acceptable

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

[7]»*Reviewer's Comments:*

The sponsor provided an Indication for Use (IFU) statement that was deficient in the following areas:

A. The sponsor did not list the model numbers of the subject device. The sponsor should clearly specify all device models and state their respective model numbers.
   - The sponsor will be asked to provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. The sponsor will be asked to include a description of the differing features between model numbers.

K101128/S001: The sponsor provided an IFU statement with an adequate description of all device models.
Conclusion: This is acceptable.

B. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007.
   - The sponsor will be asked to revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

K101128/S001: The sponsor provided an IFU statement that identified all claimed antiviral agents and indicated there intended purposes. However the IFU statement contained the following ambiguous statements:

"Active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals."

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including - Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

"These devices also help to protect the wearer from splash and spray of blood and body fluids."

- The sponsor will be asked to make the following corrections:

Replace "biologicals" with "viruses."

Remove the statement: "These devices also help to protect the wearer from splash and spray of blood and body fluids."

Remove the statement: "The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including – [virus list]." The sponsor may indicate if that the tested viruses fall into on of the listed influenza categories, but the statement should not imply that additional viruses not listed were successfully tested. The sponsor should amend this statement on the 510(k) and labeling and submit corrections for review.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 216

Conclusion: This is not acceptable.

C. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures."
   - The sponsor will be asked to revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

K101128/S001: The sponsor provided an IFU statement that replaced removed the language not found in 21 CFR 878.4040 and replaced it with: "They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and body fluids." The last sentence of this statement is addressed in the above deficiency and the other content of this statement is acceptable.
Conclusion: This is acceptable.

D. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only."
   - The sponsor will be asked to remove the above statement from the IFU; it has not been supported by performance testing.

K101128/S001: The sponsor removed this statement from the IFU.
Conclusion: This is acceptable.

E. The Indication for Use (IFU) statement did not list the influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask.
   - The sponsor will be asked to include the influenza virus strains that have been shown to be adequately reduced (>4log reduction) by the activity of the mask in the IFU statement.

K101128/S001: The sponsor included the tested viruses on the IFU statement..
Conclusion: This is acceptable.

F. The revised IFU statement should address all listed deficiencies.

K101128/S001: The sponsor has not demonstrated the antiviral performance of the copper acetate and zinc acetate in the final finished subject device.
- The sponsor will be asked to provide performance data using the final finished product that demonstrates the antiviral performance of zinc acetate and copper acetate on the claimed viruses or remove all performance claims of these compounds from the IFU and all device labeling.

Conclusion: This is not acceptable.

[8]» *Reviewer Comments:*
The sponsor provided labeling that contained the following deficiencies:

A. The sponsor provided labeling that makes broad claims about the performance of the device against influenza viruses. These claims include but are not limited to: "Inactivation of 99.99% of H1N1 influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of <u>all</u> influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim.
   - The sponsor will be asked to provide labeling that <u>only</u> includes antiviral performance claims on virus strains that demonstrated a 4 log or greater reduction during in-vitro testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

- In addition, the sponsor will be asked to provide labeling that clearly states that the in vitro antiviral activity demonstrated was only against single isolates of selected influenza virus strains.

K101128/S001: The sponsor stated that the labeling has been revised to include only virucidal performance claims relating solely to the tested virus strains, and for those that demonstrated the necessary virucidal reduction during *in vitro* testing on 5 minutes contact with the surface of the mask
Conclusion: This is acceptable.

B. The sponsor provided labeling with the claim: "Kills influenza Viruses on Contact." This claim implies an instantaneous inactivation of influenza which has not been substantiated.
   - The sponsor will be asked to remove the claim: "Kills influenza Viruses on Contact" from all labeling.

K101128/S001: The sponsor removed this claim from labeling.
Conclusion: This is acceptable.

C. The sponsor provided labeling with the claim: "BioMask kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file.
   - The sponsor will be asked to revise the above labeling claim to accurately reflect the performance data.

K101128/S001: The sponsor used revised wording: "Kills (inactivates) 99.99% of the following tested Influenza viruses on 5 minutes contact with the surface of the face mask, as tested in laboratories" in the labeling.
Conclusion: This is acceptable.

D. The sponsor included the Indication for Use (IFU) statement in the labeling. Reviewer comments 6 addresses the IFU related deficiencies.
- The sponsor will be asked to revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiency 6.

K101128/S001: The sponsor submitted an amended IFU that was deficient in several areas.
- The sponsor will be asked to include these corrections in labeling.

Conclusion: This is not acceptable.

E. The statement: "HOW IT WORKS: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported by performance data.
- The sponsor will be asked to provide supporting data or revise/remove this claim.

K101128/S001: The sponsor has not provided sufficient data to support this claim.
- The sponsor will be asked to provide supporting data or revise/remove this claim.

Conclusion: This is not acceptable.

F. The sponsor will be asked to include the following statement: No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from influenza infection."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 218

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K101128/S001: The sponsor provided labeling that include the above statement.
Conclusion: This is acceptable

G. The sponsor will be asked to address the following issues with the provided labeling:

1. Please add to the Warnings/Contraindications section a Caution that patients with hypersensitivity to citric acid, copper or zinc should not use this device.

2. Please remove all symbols from the labeling of this device unless they are accompanied by the English language explanation of the symbol.

3. The "Premium" BioMask should add the Caution that the small "ear adjuster" beads may pose a choking hazard to young children if separated from the device.

4. The sponsor should place the word "tested" in normal or larger print in the phrases below (as indicated in red) to clarify to users that only a few (18) strains of influenza have been tested against this mask.

Kills 99.9% of tested Flu Viruses tested *"
"Inactivates 99.99% of tested H1N1 influenza virus tested*"

5. The phrase "Seasonal and pandemic flu strains*including swine flu and bird flu*" appears to be too broad and deciphering the significance of the asterisks is not clear to the reader. This phrase should be revised. Adding "testing" or "tested" at the beginning could be considered.

6. "Protective" without further explanation implies a claim for protection against the disease influenza. This should be revised for clarity or deleted.

7. "Part of a range of innovative products" is not part of this submission and so should not appear in the labeling for this specific device. This phrase should be deleted.

8. The statement "How it works: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported. Please provide supporting data or remove this claim. The sponsor has not provided data to adequately support this claim yet; it should be deleted.

9. The phrase "†when used as intended" is vague and confusing as a free-standing phrase. It should be explained in detail or deleted.

10. The phrase "This mask does not contain natural latex" needs to be revised to say "natural rubber latex" for accuracy.

11. The claim "easy breathing" is a vague, ambiguous claim that could be misinterpreted. This should be removed from the labeling.

Conclusion: This is not acceptable.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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***Kills germs including those that cause Influenza A, Swine Flu, Bird Flu, common colds, measles, MRSA, pneumonia and SARS.**

K101128/S001: The sponsor stated that the above claims are associated with another product, not the subject of the submission.
Conclusion: This is acceptable.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 220

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 202

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 224

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 225

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 226

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 2007

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 229

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

K101128/S001

Date:	December 29, 2010	
To:	The Record	Office: ODE
From:	Steven Elliott Biochemistry/Physiology Reviewer	Division: DAGID
Through:	Elizabeth Claverie-Williams, Branch Chief, INCB	
510(k) Holder:	Filligent HK Limited	
	7/F 69 Jervois st. Sheung Wan, Hong Kong, HK	
Device Name:	BioFriend BioMask Surgical Face Mask.	
Contact:	Melissa Mowbray-D'Arbela	
Phone:	852-2542-2400	
Fax:	852-2542-2411	
Email:	melissa@filligent.com	

We have completed our review of the supplement to the above referenced 510(k). We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you have provided. To complete the review of this submission, please provide a response to the following questions and/or recommendations.

In order to continue our review of this submission, we request the following:

510(k) summary:

1. In the Indications for Use/Statement of Intended Use added to the 510(k) Summary, the phrase "Which form.....on biologicals" is incorrect. Performance testing on this device has examined only influenza viruses. Please replace "biologicals" with "influenza viruses."

2. In the Indications for Use/Statement of Intended Use added to the 510(k) Summary, the phrase "...tests against seasonal, pandemic, avian, swine and equine Influenza viruses including..." is misleading because it implies that additional strains of virus have been tested. Please revise this statement to "...tests against these specific Influenza virus strains – Influenza A H1N1 (A/California/07/2009 (2009 pandemic strain), A Brisbane/59/2007..."

3. Please provide the exact scientific strain identification for "Avian Influenza H9N2."

4. Please remove the sentence "These devices also help to protect the wearer from splash and spray of blood and body fluids" as previously requested. This wording is not included in 21 CFR 878.4040.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 231

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layers. The use of a high titer viral challenge is recommended in order to clearly show the antiviral efficacy of each version of the device.

Indications for Use Statement:

7. Please amend your indication for use statement to include the following corrections:

- The phrase "Which form.....on biologicals" is incorrect. Performance testing on this device has examined only influenza viruses. Please replace "biologicals" with "influenza viruses."
- The phrase "...tests against seasonal, pandemic, avian, swine and equine Influenza viruses including..." is misleading because it implies that additional strains of virus have been tested. Please revise this statement to "...tests against these specific Influenza virus strains – Influenza A H1N1 (A/California/07/2009 (2009 pandemic strain), A Brisbane/59/2007..."
- Please remove the sentence "These devices also help to protect the wearer from splash and spray of blood and body fluids" as previously requested. This wording is not included in 21 CFR 878.4040.
- Please provide the exact scientific strain identification for "Avian Influenza H9N2."
- You have not yet demonstrated adequate antiviral performance of the copper acetate and zinc acetate in the final finished subject device. Please provide performance data using the final finished product that demonstrates the antiviral performance of zinc acetate and copper acetate on the claimed viruses.

Labeling:

8. On the device labeling, you have used a much smaller font size to indicate that the mask kills 99.9% of tested flu viruses. This may be misleading. Please place the word "tested" in normal or larger print in the phrases below (as indicated in red) to clarify to users that only a few (18) strains of influenza have been tested against this mask.

Kills 99.9% of tested Flu Viruses **tested** *"
"Inactivates 99.99% of tested H1N1 influenza virus **tested***"

9. In the revised device labeling, the phrase "Seasonal and pandemic flu strains*including swine flu and bird flu*" appears to be too broad and deciphering the significance of the asterisks may be difficult for the reader. This phrase should be revised since, as presently written, it does not clearly state that the BioMask has been tested only against certain influenza strains. Adding "testing" or "tested" at the beginning could be considered.

10. "Protective" without further explanation implies a claim for protection against the disease influenza. This should be revised to make it very clear that no clinical benefit from the use of this device has been demonstrated.

11. "Part of a range of innovative products" is not part of this submission which included only a single device and so should not appear in the labeling for this specific device. Please delete this phrase.

12. The label statement "How it works: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not yet been supported. It is not yet clear how many viable influenza viruses reach the 2nd layer to be killed there. Please provide supporting data or remove this claim.

13. The phrase "†when used as intended" is vague and confusing as a free-standing phrase. Please explain this instruction in detail or delete it.

14. The phrase "This mask does not contain natural latex" should be revised to say "natural rubber latex" for accuracy.

15. Please add a Caution to the device labeling which advises persons with hypersensitivity to copper or zinc to avoid the use of this device.

16. Please remove all symbols from the labeling of this device unless they are accompanied by the English language explanation of the symbol.

17. The "Premium" BioMask should add the Caution that the small "ear adjuster" beads may pose a choking hazard to young children if separated from the device. This device should be kept away from children and discarded in a manner which keeps it away from them.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

- The acceptance criteria for each assay used

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 234

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016

COVER SHEET MEMORANDUM

From: Reviewer Name Steven Elliott

Subject: 510(k) Number K101128

To: The Record

Please list CTS decision code AI

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc.)
- ☑ Hold (Additional Information or Telephone Hold).
- ☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

7/2/07

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Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Adly (Branch Chief) NCB (Branch Code) 05/21/10 (Date)

Final Review:

(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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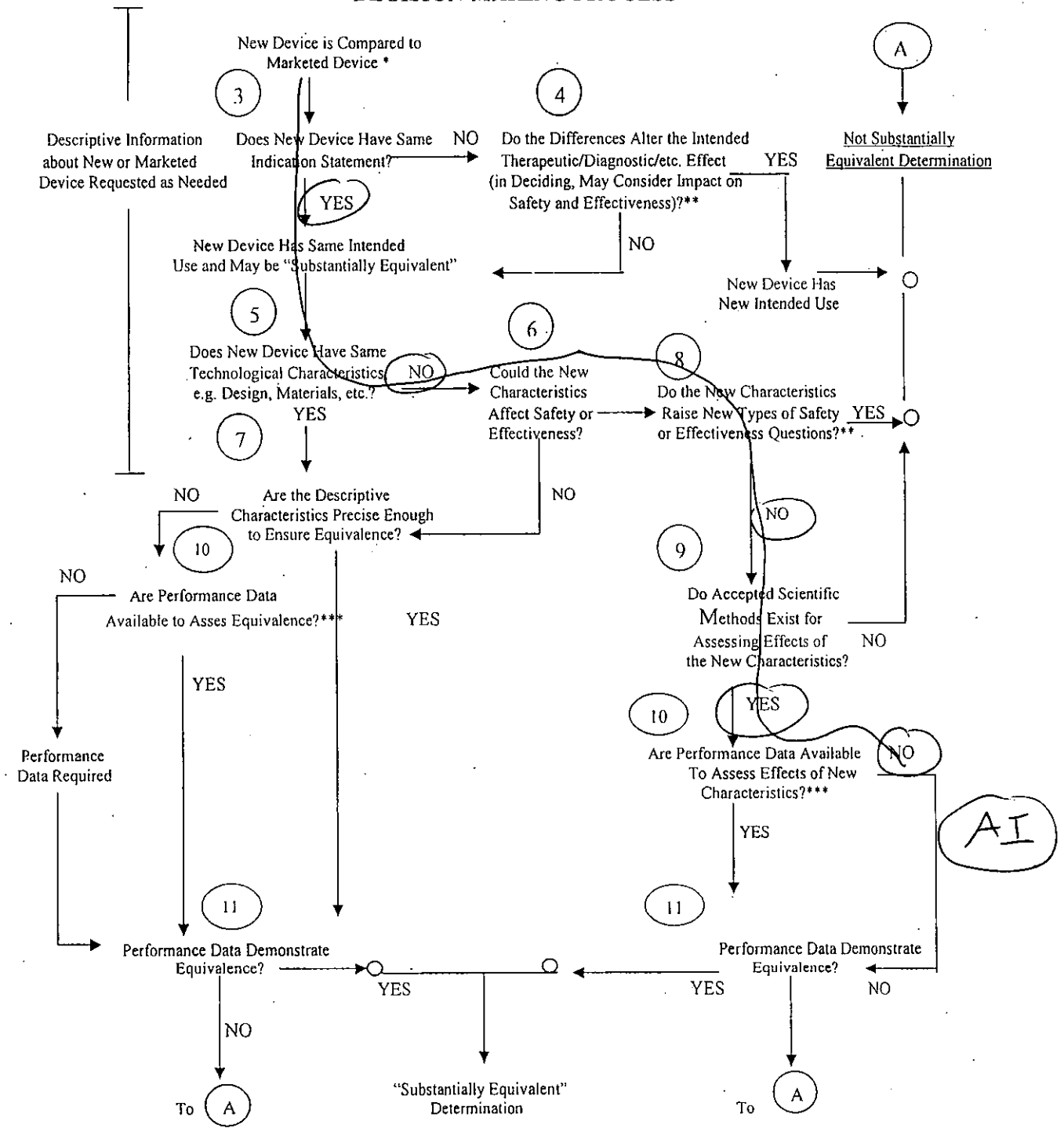
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center -- WO66-G609
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional

K101128

Date:	May 21, 2010	
To:	The Record	Office: ODE
From:	Steven Elliott Biochemistry/Physiology Reviewer	Division: DAGID
Through:	Dr. Geetha Jayan, PhD, Acting Branch Chief, INCB	
510(k) Holder:	Filligent HK Limited	
	7/F 69 Jervois st. Sheung Wan, Hong Kong, HK	
Device Name:	BioFriend BioMask Surgical Face Mask.	
Contact:	Melissa Mowbray-D'Arbela	
Phone:	852-2542-2400	
Fax:	852-2542-2411	
Email:	melissa@filligent.com	

I. Purpose and Submission Summary

Filligent HK Limited would like to introduce the "BioFriend BioMask Surgical Face Mask." into interstate commerce. The firm has submitted a pre-market notification (PMN) [510(K)] for the device.

The firm claims that the "BioFriend BioMask Surgical Face Mask" is a Class II surgical face mask (21 CFR 878.4040), product code FXX).

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page OTC	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Data Report Form – Form 3654		√	

Medical Device Standards Referenced:

1. ASTM F2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks.
2. ASTM F2101: 2007 Standard Test method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask materials Using a Biological Aerosol of Staphylococcus aureus.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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3. ASTM F2299: 2003 Standard Test method for determining the initial efficiency of materials used in Medical Face Masks to Penetration by Particles Using Latex Spheres.
4. ASTM F1862: 2007 Standard Test Method for Resistance of Medical Facemasks to Penetration by Synthetic Blood. (Horizontal Projection of Fixed Volume at a Known Velocity)
5. MIL-M-36954C Military Specification, Surgical Mask, Disposable.
6. ISO 10993-10E:2002 Biological Evaluation of Medical Devices— Part 10 Tests for irritation and delayed-type hypersensitivity. – Listed as 2003 in the Standards Data Report for 510(k)s.
7. ISO 10993-18 Biological Evaluation of Medical Devices— Part 18 Chemical characterization of materials.
8. ASTM E1052-96 Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension.

[1]» *Reviewer Comments:*
The sponsor provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard.

- The sponsor will be asked to provide a new Standards Data Report for 510(k)s form for this standard that cites conformance to ISO 10993-10:2002 This form can be found at: **http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf**

This is not acceptable.

The firm has provided its 510(k) Summary in section 5 of the submission:

			YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)					
	Clearly labeled "510(k) Summary"		√		
	Submitter' s name, address, phone #, a contact person		√		
	Date the summary was prepared		√		
	The name of the device/trade name/common name/classification name		√		
	An identification of the legally marketed Predicate		√		
	Description of the subject device			√	
	Statement of intended use (identical to indications for use)		√		
	Technological characteristics	if same, a summary of comparison of technological characters		√	
		If different, a summary of how do they compare to the Predicate		√	
	Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	√		
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ Description upon whom the device was tested, ▪ Data obtained from the tests and especially: ▪ Adverse events and complications ▪ Other information for SE determination			√
		Conclusion that data demonstrate SE	√		
Required Elements for 510(k) Statement (21 CFR 807.93)					
	Signed verbatim statement				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[2]» *Reviewer Comments:*
The sponsor provided a 510(k) summary that did not contain an adequate description of the subject device. The sponsor did not indicate the subject device models or explain the differences between all subject models intended for clearance.

- The sponsor will be asked to provide an amended 510(k) summary that lists the model numbers of all devices intended for clearance in this submission and explains all differences between all device models and predicates. The sponsor will be asked to ensure that the amended 510(k) summary addresses all related deficiencies in this memorandum.

This is not acceptable.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		√	

The sponsor provided the following description:

Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. The outer layer is coated with a hydrophilic plastic. The second layer is treated with copper and zinc. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip. One model is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard "comfort" features such ear adjusters and an anti-fog nose insert.

Universal BF-200-2001:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 343

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4)

[4]» *Reviewer Comments:*

(b)(4)

(b)(4)

In response to the FDA's email request for additional descriptive information April 26, 2010, the sponsor provided MSDS reports for the following mask components:

(b)(4)

sponsor provided the following dimensions for the subject masks:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 345

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(b)(4)

[redacted]

IV. Indications for Use

The sponsor provided the following information in the Indication for Use Statement:

Device Name:
BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001 and Premium BF-200-3013

Indications for Use:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices intended to be worn in the operating room as well as during dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of micro-organisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

The sponsor indicated over-the-counter use.

[6]»*Reviewer's Comments:*

The sponsor provided an Indication for Use (IFU) statement that was deficient in the following

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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areas:

A. The sponsor did not list the model numbers of the subject device. The sponsor should clearly specify all device models and state their respective model numbers.
   - The sponsor will be asked to provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. The sponsor will be asked to include a description of the differing features between model numbers.

B. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007.
   - The sponsor will be asked to revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

C. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures."
   - The sponsor will be asked to revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

D. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only."
   - The sponsor will be asked to remove the above statement from the IFU; it has not been supported by performance testing.

E. The Indication for Use (IFU) statement did not list the influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask.
   - The sponsor will be asked to include the influenza virus strains that have been shown to be adequately reduced (>4log reduction) by the activity of the mask in the IFU statement.

F. The revised IFU statement should address all listed deficiencies.

This is not acceptable.

V. Predicate Device Comparison

The firm provided the following information for comparison of the submission with the predicate device:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

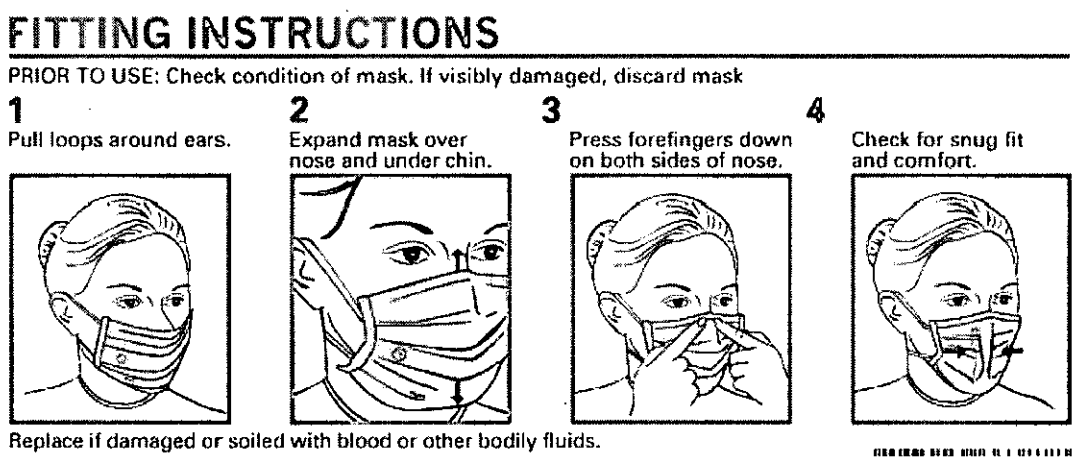
(b)(4)

[redacted]

VI. Labeling

The sponsor provided the package labeling (individual package and box) for both mask models. Samples of the labeling are included below:

The sponsor included the following instructions on the labeling:



(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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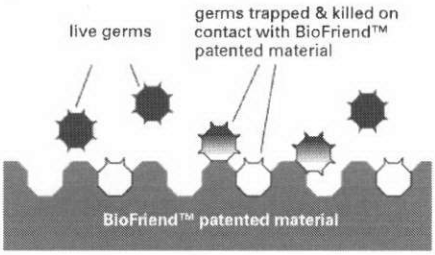
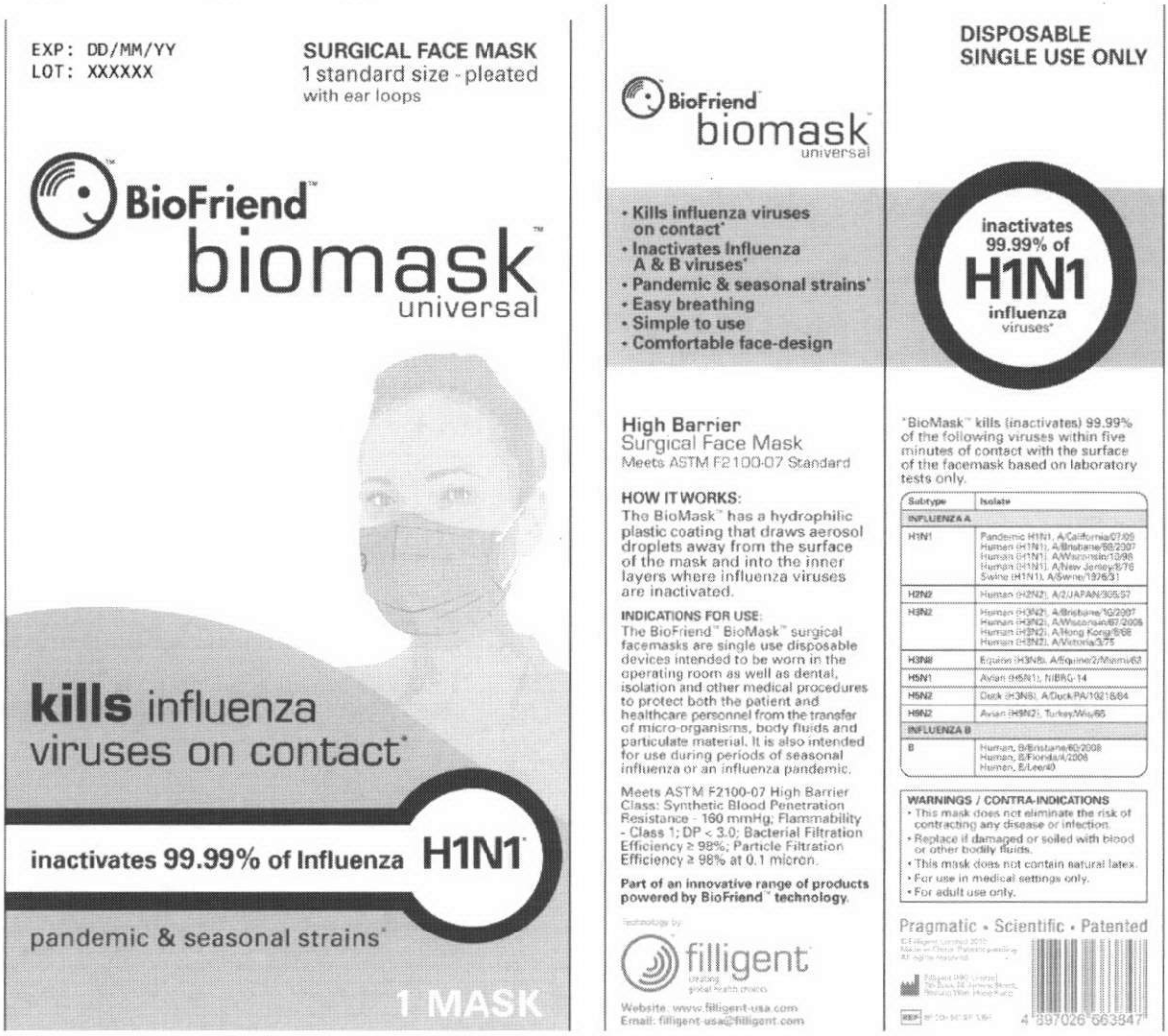
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Replace after 12 hours of active wear or earlier, if damaged or soiled with blood or bodily fluids.



Single Use Package Labeling:



[7]» *Reviewer Comments*:

The sponsor provided labeling that contained the following deficiencies:

A. The sponsor provided labeling that makes broad claims about the performance of the device against influenza viruses. These claims include but are not limited to: "Inactivation of

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 350

99.99% of H1N1 influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of all influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim.

- The sponsor will be asked to provide labeling that only includes antiviral performance claims on virus strains that demonstrated a 4 log or greater reduction during in-vitro testing.
- In addition, the sponsor will be asked to provide labeling that clearly states that the in vitro antiviral activity demonstrated was only against single isolates of selected influenza virus strains.

B. The sponsor provided labeling with the claim: "Kills influenza Viruses on Contact." This claim implies an instantaneous inactivation of influenza which has not been substantiated.

- The sponsor will be asked to remove the claim: "Kills influenza Viruses on Contact" from all labeling.

C. The sponsor provided labeling with the claim: "BioMask kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file.

- The sponsor will be asked to revise the above labeling claim to accurately reflect the performance data.

D. The sponsor included the Indication for Use (IFU) statement in the labeling. Reviewer comments 6 addresses the IFU related deficiencies.

- The sponsor will be asked to revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiency 6.

E. The statement: "HOW IT WORKS: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported by performance data.

- The sponsor will be asked to provide supporting data or revise/remove this claim.

F. The sponsor will be asked to include the following statement: No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from influenza infection."

This is not acceptable.

[8]» *Reviewer Comments*:

The online brochure contains numerous claims associated witha BioMask device that appears to be the subject of the submission. These claims are not substantiated by data in this 510(k) submission. The claims include:

BioFriend's revolutionary, patented technology traps and kills bacteria and viruses on contact AND allows you to breathe normally:

• Traps and kills 99.9% of harmful germs

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• Superior breathability & comfort
• Self-sanitizing for ALL-DAY WEAR
• Reduces cross-contamination of hands and surfaces
• Standard and small sizes

***Kills germs including those that cause Influenza A, Swine Flu, Bird Flu, common colds, measles, MRSA, pneumonia and SARS.**

BioFriend™ traps microbes by mimicking the sites on human cells to which they normally attach, then, destroys them by disrupting their surfaces (viruses) or cell walls (bacteria).

- The sponsor will be asked to please clarify if these claims are intended for the subject of this submission as they have not been supported by data.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 352

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(b)(4)

[redacted]

VIII. Biocompatibility
Discussed in Performance Testing – Animal. Refer to Section XI.

IX. Software
N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
N/A

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

354

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 355

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118 356

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 358

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 359

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

XIII. Performance Testing – Clinical

N/A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		√	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		√	If **YES** = Stop **NSE**
3. Same Technological Characteristics?		√	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	√		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		√	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	√		If **NO** = Stop **NSE**
8. Performance Data Available?		√	**If NO = Request Data**
9. Data Demonstrate Equivalence?			Final Decision: TH

Note: Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain what performance data is needed:
8. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

In order to continue our review of this submission, we request the following:

[1]» *Reviewer Comments:*

The sponsor provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard.

- The sponsor will be asked to provide a new Standards Data Report for 510(k)s form for this standard that cites conformance to ISO 10993-10:2002 This form can be found at: **http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf**

This is not acceptable.

[2]» *Reviewer Comments:*

The sponsor provided a 510(k) summary that did not contain an adequate description of the subject device. The sponsor did not indicate the subject device models or explain the differences

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(b)(4)

[3]» *Reviewer Comments:*

(b)(4)

[6]»*Reviewer's Comments:*

The sponsor provided an Indication for Use (IFU) statement that was deficient in the following areas:

A. The sponsor did not list the model numbers of the subject device. The sponsor should clearly specify all device models and state their respective model numbers.

- The sponsor will be asked to provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. The sponsor will

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 312

be asked to include a description of the differing features between model numbers.

B. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007.
   - The sponsor will be asked to revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

C. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures."
   - The sponsor will be asked to revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

D. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only."
   - The sponsor will be asked to remove the above statement from the IFU as the reason for this recommendation is not clearly stated.

E. The Indication for Use (IFU) statement did not list the influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask.
   - The sponsor will be asked to include the influenza virus strains that have been shown to be adequately reduced (>4log reduction) by the activity of the mask in the IFU statement.

F. The revised IFU statement should address all listed deficiencies.

This is not acceptable.

[7]» *Reviewer Comments*:

The sponsor provided labeling that contained the following deficiencies:

A. The sponsor provided labeling that makes broad claims about the performance of the device against influenza viruses. These claims include but are not limited to: "Inactivation of 99.99% of H1N1 influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of <u>all</u> influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim.
   - The sponsor will be asked to provide labeling that <u>only</u> includes antiviral performance claims on virus strains that demonstrated a 4 $\log_{10}$ or greater reduction during in-vitro testing.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 363

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

- In addition, the sponsor will be asked to provide labeling that clearly states that the in vitro antiviral activity demonstrated was only against single isolates of selected influenza virus strains.

B. The sponsor provided labeling with the claim: "Kills influenza Viruses on Contact." This claim implies an instantaneous inactivation of influenza which has not been substantiated.
   - The sponsor will be asked to remove the claim: "Kills influenza Viruses on Contact" from all labeling.

C. The sponsor provided labeling with the claim: "BioMask kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file.
   - The sponsor will be asked to revise the above labeling claim to accurately reflect the performance data.

D. The sponsor included the Indication for Use (IFU) statement in the labeling. Reviewer comments 6 addresses the IFU related deficiencies.
- The sponsor will be asked to revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiency 6.

E. The statement: "HOW IT WORKS: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported by performance data.
- The sponsor will be asked to provide supporting data or revise/remove this claim.

F. The sponsor will be asked to include the following statement: No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from influenza infection."

This is not acceptable.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ traps microbes by mimicking the sites on human cells to which they normally attach, then, destroys them by disrupting their surfaces (viruses) or cell walls (bacteria).

- The sponsor will be asked to please clarify if these claims are intended for the subject of this submission as they have not been supported by data.

This is not acceptable.

(b)(4)

[redacted]

[11]» *Reviewer Comments:*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Filligent HK Limited
C/O Melissa Mowbray-D'Arbela
Chief Executive Officer,
Emergo Group, Incorporated
7th Floor, 69 Jervois St.,
Sheung Wan, Hong Kong

Re: K101128
Trade Name: BioFriend BioMask
Dated: April 20, 2010
Received: April 22, 2010

Dear Ms. Mowbray-D'Arbela:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require additional effectiveness and safety testing information on the subject device. We also require additional general/administrative information on the subject device and clarifications in the labeling of the device.

The deficiencies listed on the following pages are organized into different sections. We request that you carefully review these deficiencies before you formulate your responses.

Also, please be advised that we may have additional concerns regarding your labeling and indications for use statement after we receive additional information on this submission from you.

We understand that the preparation of a 510(k) submission for a new type of device such as the BioFriend™ BioMask™ can be a complex undertaking. You may find it helpful to discuss the deficiencies listed below with the FDA, to understand what information is being requested and the means by which you can respond to the deficiencies. The Division would be happy to discuss this with you either by teleconference or in a face to face meeting, whichever is more convenient for you.

To schedule a meeting or a teleconference with FDA, please contact Steven Elliott, M.S., Reviewer, Infection Control Devices Branch at (301) 796-5285 or by email at steven.elliott@fda.hhs.gov.

To complete the review of this submission, we ask that you address the deficiencies listed in this letter and provide the additional information requested. Please provide an item-wise response to each deficiency.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 369

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 370

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. Please include a description of the differing features between model numbers.

8. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007. Please revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

9. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures." Please revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

10. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only." Please remove the above statement from the IFU as testing to support such claim is not provided in the submission.

11. The Indication for Use (IFU) statement did not list the influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask. Please include the influenza virus strains that have been shown to be adequately reduced ($\geq$4 log reduction) by the activity of the mask in the IFU statement.

12. Please ensure that the revised IFU statement addresses all listed deficiencies.

Labeling:

13. You provided labeling that makes broad claims about the performance of the device against influenza viruses. These claims include but are not limited to: "Inactivation of 99.99% of H1N1 influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of all influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim. Please provide labeling that only includes antiviral performance claims on virus strains that demonstrated a 4 $\log_{10}$ or greater reduction during in-vitro testing.

14. You provided labeling with the claim: "Kills influenza Viruses on Contact." This claim implies an instantaneous inactivation of influenza which has not been substantiated. Please remove the claim: "Kills influenza Viruses on Contact" from all labeling.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 371

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15. You provided labeling with the claim: "BioMask™ kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file. Please revise the above labeling claim to accurately reflect the performance data.

16. You included the Indication for Use (IFU) statement in the labeling. Deficiencies 7 - 11 address the IFU related deficiencies. Please revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiencies 7 – 11.

17. The statement: "HOW IT WORKS: The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated" has not been supported by performance data. Please provide supporting data or revise/remove this claim.

18. Please include the following statement in the device labeling: "No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from influenza infection."

(b)(4)

[redacted]

Please clarify if these claims are intended for the subject of this submission.

Shelf Life:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 372

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 373

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. .

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Steven Elliott at (301) 796-5285. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 375

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toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Geetha C. Jayan, Ph.D.
Branch Chief, Infection Control Devices Branch]
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date

K101128

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 376

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Consultation Review

Document Number: K101128
Device Name: BioFriend BioMask
Sponsor: Filligent HK Limited

Reviewer: Sheila A. Murphey, MD
Medical Officer, INCB

Date: May 7, 2010

Subject

Filligent HK Ltd has submitted K101128 to introduce its BioFriend™ BioMask™ (2 models) into interstate commerce.

Device Description

The BioFriend BioMask is submitted as two models. One is a pleated surgical mask with ear loops (Universal BF-200-2001) and the other is a convex mask with ear loops which opens from a middle fold and has beads on the ear loops for fit adjustment (Premium BF-200-3013).

The sponsor describes the two mask models as "identical in all respects other than shape. This is not completely accurate - see below. The dimensions of the two models are not provided. Both models have 4 layers of the same materials. The outermost layer is spun-bond polypropylene with a coating of partially hydrolyzed polyvinyl alcohol, citric acid and Tween 20, described as a hydrophilic plastic. The second layer is spun-lace cellulose/polyester textile dyed with CI Reactive Blue 21 and then soaked with 1%w/w copper acetate and 1% w/w zinc acetate for a final composition of 2.25 w/w CI Reactive Blue 21, 1.6% w/w copper and 1.6% zinc. The third layer is melt-blown polypropylene filter material. The fourth layer is spun-bound polypropylene.

The ear loops on both masks are described as "latex-free" elastic loops. The ear loops on the convex Premium BF-200-3013 mask have polypropylene ear adjuster beads. Both masks have malleable nosepiece strips which differ in composition. The Universal BF-200-2001 pleated facemask has a nosepiece made of steel wire laminated with plastic. The nosepiece on the Premium BF-200-3013 convex mask is made of malleable aluminum wire with a nosepiece sponge insert of polyurethane foam. This nosepiece is described as an "anti-fog nose insert".

Both masks are described as single use, disposable devices.

All performance testing used only the Premium BF-200-3013 convex mask model.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Both BioFriend BioMask devices are described as having anti-viral activity against influenza A and B strains. However, the relative roles of the three potentially antiviral compounds are not clearly delineated and the minimal inhibitory concentration (MEC) of the antimicrobial agents is not provided.

(b)(4)

[redacted]

The sponsor describes the anti-viral action as "the durable plastic coating decreases the hydrophobicity of the outer layer and thereby increases the transmission of aerosol droplets into a juxtaposed and inner layer of the mask where influenza viruses are inactivated by the divalent metal ions copper and zinc and low pH".

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 379

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 380

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(b)(4)

[redacted]

Indication for Use

The BioFriend BioMask surgical facemasks are single use disposable devices intended to be worn in the operating room as well as during dental, isolation and other medical procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The masks are also intended for use during periods of seasonal influenza or an influenza pandemic, based on laboratory tests only.

Reviewer Comment

The Indication for Use (IFU) statement does not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007. It should be revised to add this information.

The sponsor should also remove the wording not found in 21 CFR 878.4040 "as well as during dental, isolation and other medical procedures".

The sponsor should also replace the additional wording of the regulation "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer".

The statement concerning wearing these devices during periods of seasonal or pandemic influenza must be revised. The reason for this recommendation is not clearly stated.

Labeling

The following statements in the proposed device labeling must be revised since they are both too broad and too vague:

"Kills influenza virus on contact*" "*pandemic and seasonal strains"

"Inactivates 99.99% of Influenza H1N1"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Inactivates Influenza A & B viruses"

"How it Works: The BioMask has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are inactivated"

"BioMask kills (inactivates) 99.99% of the following viruses ***within*** five minutes of contact with the surface of the facemask based on laboratory tests only"

Listing for activity against influenza B/Brisbane 60/2008 - this agent was not inactivated at a log 4 reduction level (not 99.99%).

Indications for Use statement is included and is in need of revision as noted above.

Reviewer Comment

The labeling of this device must clearly state that the in vitro antiviral activity demonstrated was only against single isolates of selected influenza virus strains.

Only influenza virus strains for which a 4 log or greater reduction during in-vitro testing should be claimed as antiviral performance.

Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file. The sponsor should not say "within" 5 minutes; data to support such a claim has not been provided in this file.

The current "Indications for Use" statement has been included in this labeling; it should be revised as noted above.

The "How It Works" statement has not been supported by performance data submitted in this file. It should be supported by data or revised/deleted.

The labeling should include the following statement "No clinical studies have been conducted comparing the ability of an uncoated face mask and this face mask to protect the wearer from influenza infection".

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

7. The Indication for Use (IFU) statement does not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007. These should be revised to add this information.

8. The sponsor should also remove the wording from the IFU not found in 21 CFR 878.4040 "as well as during dental, isolation and other medical procedures".

9. The sponsor should also replace the additional wording of the regulation "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer".

10. The statement concerning wearing these devices during periods of seasonal or pandemic influenza should be revised. The reason for this recommendation is not clearly stated.

11. The specific strains of influenza virus against which adequate antiviral activity has been demonstrated should be included in the IFU statement.

12. The labeling of this device should clearly state that the in vitro antiviral activity demonstrated was only against single isolates of selected influenza virus strains.

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 390

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4)

[redacted]

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

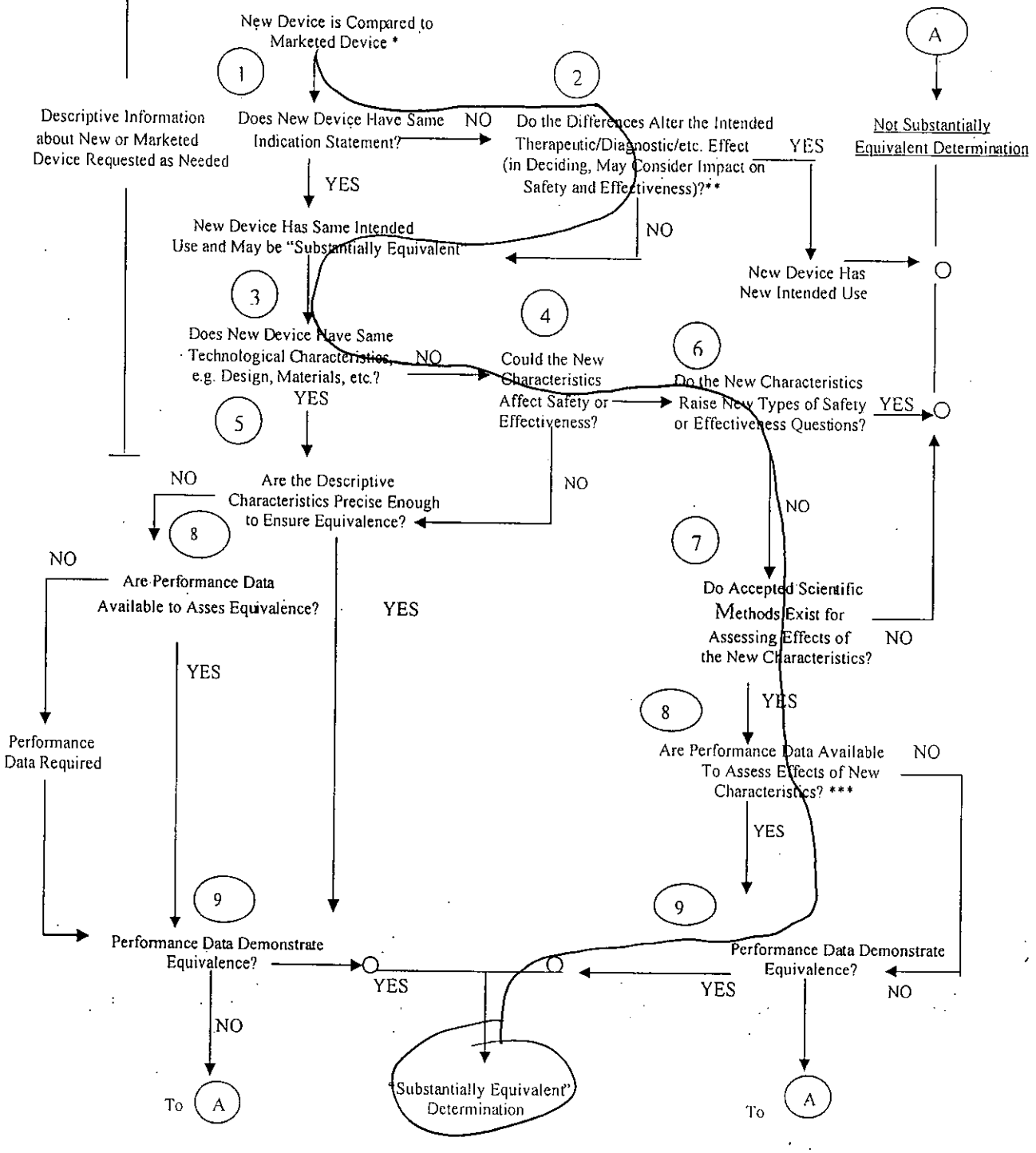
Sheila A Murphey MD 5/19/10

Sheila A. Murphey, MD
Medical Officer, INCB
May 8, 2010

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



SE

* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent

K101128/S1

November 13, 2010

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information - 510(k) Premarket Notification – K101128

With reference to the CDRH's request for Additional Information, dated May 21, 2010, Filligent (HK) Limited would like to replace the letter provided to the CDRH on November 10, 2010 and incorrectly labeled as "Add to File", with the submission contained herein and correctly labeled as "Additional Information".

Each request is listed in the following pages, together with our response.

We believe that this response will provide adequate information to reach a determination of substantial equivalence. Nevertheless, if you require additional information, please do not hesitate to contact us at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

FDA CDRH OMC
NOV 15 2010
Received

K-60

Sincerely

Kathy S. Kukreja
Legal Counsel
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent

November 10, 2010

K101128/S1

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Add-to-File - 510(k) Premarket Notification – K101128

This letter constitutes Filligent (HK) Limited's response to CDRH's request for additional information, which was dated May 21, 2010. Each request is listed in the following pages, together with our response.

We believe that this response will provide adequate information to reach a determination of substantial equivalence. Nevertheless, if you require additional information, please do not hesitate to contact us at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

FDA CDRH/OIC
NOV 12 2010
Received

F-33

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent
creating
global health choices

November 13, 2010

Document Mail Center - WO66-0609
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Filligent (HK) Limited

7th Floor, 69 Jervois Street

Sheung Wan, Hong Kong

Telephone: +852 2542 2400

Fascimile: +852 2542 2411

Email: melissa@filligent.com

Sincerely

Kathy S. Kukreja
Legal Counsel
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

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- Questions 30 to 32

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

1 Administrative

CDRH Questions

1. You provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard. Please provide a new Standards Data Report for 510(k) form for this standard that cites conformance to ISO 10993-10:2002. This form can be found at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf

2. You provided a 510(k) summary that did not contain an adequate description of the subject device. You did not indicate the subject device models or explain the differences between all subject models intended for clearance. Please provide an amended 510(k) summary that lists the model numbers of all devices intended for clearance in this submission and explains all differences between all device models and predicates. Please ensure that the amended 510(k) summary addresses all related deficiencies in this memorandum.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

1. You provided a Standards Data Report for 510(k)s (FDA form 3654) for the ISO 10993-10:2003. This is not the active ISO standard. Please provide a new Standards Data Report for 510(k)s form for this standard that cites conformance to ISO 10993-10:2002. This form can be found at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf

The amended Standards Data Report for ISO10993-10:2002 is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993 Biological Evaluation of Medical Devices - Part 10 Tests for Irritation - In vivio. 2002

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 2-87	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☑
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Surgical Masks - Premarket Notification [510(k)] Submission

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993 Biological Evaluation of Medcial Devcies - Part 10: Tests for Irritation - In vivvo. 2002

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation Test	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
6.3 Animal skin irritation test

DESCRIPTION
An assessment is made of the potential of the material under test to produce dermal irritation in a relevant animal model

JUSTIFICATION
Method used by predicate devices and other similar marketed devcies allows for comparative evaluation of irritation data

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation Test	☐ Yes ☑ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
6.4 Human skin irritation test

DESCRIPTION
An assessment is made of potential of the material under test to cause human cutaneous irritation

JUSTIFICATION
Frequently used for chemicals to which human exposure is high, typically detergents and cosmetics

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed Hypersensitivity Tests	☐ Yes ☑ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
7.4 Maximisation test for delayed hypersensitivity

DESCRIPTION
An assessmnent is made of the potential of the material under test to produce skin sensitization in guinea pigs

JUSTIFICATION
Method prefered for single chemicals

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation - In vivo. 2002

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed Hypersensitivity Tests	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
7.5 Closed-patch test for delayed hypersensitivity

DESCRIPTION
An assessment is made of the potential of the material under test to produce skin sensitization in guinea pigs

JUSTIFICATION
Method used by predicate devices and other similar marketed devcies allows for comparative evaluation of sensitization data

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5 510(k) Summary

5.1 Applicant and Correspondent

Name:	Filligent (HK) Limited
Address:	7th Floor, 69 Jervois Street Sheung Wan Hong Kong
Contact Person:	Melissa Mowbray-d'Arbela Chief Executive Officer
Phone:	(852) 2542 2400
Date of Preparation:	November 10, 2010

5.2 Manufacturer

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

5.3 Name of Device

Trade/Proprietary/Model Name:	BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001A Premium BF-200-3013A
Common Name:	Surgical Facemask
Classification Name:	Mask, Surgical
Classification Regulation:	878.4040
Panel:	General Hospital
Product Code:	FXX
Recognized Performance Std:	ASTM F2100-07 (refer to submission)

5.4 Devices to Which New Device is Substantially Equivalent

Device Name:	Prestige Ameritech Face Mask
Manufacturer:	Prestige Ameritech
Reference:	K061716

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.5 Device Description

The BioFriend™ BioMask™ surgical facemask is offered in two mask styles, Model: BF-200-2001A ("Universal") and Model: BF-200-3013A ("Premium"). The Universal model is a standard flat mask with pleats, while the Premium model is flat-folded and expands into a convex-shaped mask. The Premium model also has ear adjusters and an anti-fog nose flap. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in these devices are typical construction materials commonly used in surgical facemasks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second inner layer is treated with copper and zinc. Both layers capture and inactivate viruses. Masks are held in place on the wearer with elastic loops and contain a malleable metal nosepiece strip.

5.6 Statement of Intended Use

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including - Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions.

There are two models: (1) Universal (BF-200-2001A) - is a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and body fluids.

5.7 Summary of Technological Characteristics

The BioFriend™ BioMask™ surgical facemasks have the same filter and barrier properties as the predicate device, and conform to the recognized FDA consensus standard ASTM F2100-07 Standard Specification for Performance of Materials used in Medical Face Masks. Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. The outer layer of both models is coated with a hydrophilic plastic that allows aerosolized droplets on the surface of the mask to be absorbed into the inner layers. Both the outer and second inner layers are treated with compounds that inactivate viruses. Laboratory *(in vitro)* test results demonstrate that the BioFriend™ BioMask™ surgical facemasks kill ("inactivate") 99.99% of 18 different strains of Influenza A and B viruses, including the circulating 2009 pandemic H1N1, recent vaccine isolates, major reassortments and avian, swine and equine isolates on 5 minutes contact with the mask surface.

The BioFriend™ BioMask™ surgical facemasks have been tested for, and appropriately passed standardized tests for, fluid penetration resistance, particulate filtration efficiency, bacterial filtration efficiency, flammability, and breathing resistance. The device as a whole has been shown to be biocompatible through standardized tests for irritation, sensitization and extractables.

The materials of construction use in the BioFriend™ BioMask™ surgical facemasks are equivalent to those of the predicate device. The devices as a whole are substantially equivalent to the predicate device.

5.8 Brief description of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

- Bacterial Filtration Efficiency – ASTM F2101
- Sub-micron Particulate Filtration Efficiency – ASTM F2299
- Fluid Penetration Resistance – ASTM F1862
- Breathing Resistance – MIL-M-3654C
- Flammability Testing – 16 CFR 1610
- Biocompatibility, Irritation – ISO 10993-10
- Biocompatibility, Sensitization – ISO 10993-10
- Biocompatibility, Chemical Characterization – ISO 10993-18

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.9 Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Not applicable.

5.10 Conclusions drawn from the nonclinical and clinical tests

Standardized testing has shown that the construction materials used in both models of the BioFriend™ BioMask™ surgical facemask are substantially equivalent to those of the predicate device. The devices as a whole have been demonstrated to be biocompatible through irritation and sensitization testing, with toxicological assessment of the devices' ingredients which could potentially be released with inhalation or salivary contact, indicating the devices are safe for use in the intended application. Laboratory testing has demonstrated the devices' efficacy. Both models of the BioFriend™ BioMask™ surgical facemask have been shown to be substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Deficiencies and Responses to Deficiencies

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3 Indications for Use

Questions

7. You provided an Indication for Use (IFU) statement that did not list the model numbers of the subject device. You should clearly specify all device models and state their respective model numbers. Please provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. Please include a description of the differing features between model numbers.

8. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007. Please revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

9. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures." Please revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

10. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal Influenza or an Influenza pandemic, based on laboratory tests only." Please remove the above statement from the IFU as testing to support such claim is not provided in the submission.

11. The Indication for Use (IFU) statement did not list the Influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask. Please include the Influenza virus strains that have been shown to be adequately reduced (≥4-log reduction) by the activity of the mask in the IFU statement.

12. Please ensure that the revised IFU statement addresses all listed deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

7. You provided an Indication for Use (IFU) statement that did not list the model numbers of the subject device. You should clearly specify all device models and state their respective model numbers. Please provide a new Indication for Use Statement that lists the model numbers of every version of the subject device intended for clearance under this 510(k) submission – including sizes, colors and model designs. Please include a description of the differing features between model numbers.

The Indications for Use Statement has been revised to include the wording: "There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded and expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap."

The amended Indications for Use Statement is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

8. The IFU statement did not indicate the presence of the antiviral materials or their purpose, as advised in the "Draft Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents", issued 7/2007. Please revise the IFU Statement to include all claimed antiviral agents and their intended purposes.

The Indications for Use Statement has been revised to include the wording: "The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals)".

The amended Indications for Use Statement is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

9. The IFU statement contained the wording: "as well as during dental, isolation and other medical procedures." Please revise the IFU to remove the wording from the IFU not found in 21 CFR 878.4040: "as well as during dental, isolation and other medical procedures," and replace the omitted portion of the regulation: "worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer."

The Indications for Use Statement has been revised to include the wording: "They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and body fluids."

The amended Indications for Use Statement is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

10. The Indication for Use (IFU) statement contained the wording: "The masks are also intended for use during periods of seasonal Influenza or an Influenza pandemic, based on laboratory tests only." Please remove the above statement from the IFU as testing to support such claim is not provided in the submission.

The wording: "The masks are also intended for use during periods of seasonal Influenza or an Influenza pandemic, based on laboratory tests only", has been removed from the Indications for Use Statement.

The amended Indications for Use Statement is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

11. The Indication for Use (IFU) statement did not list the Influenza virus strains that were shown to be significantly reduced in the antimicrobial testing of the subject mask. This information should be provided to accurately describe the performance of mask. Please include the Influenza virus strains that have been shown to be adequately reduced (≥4.0-log reduction) by the activity of the mask in the IFU statement.

The Indications for Use Statement has been revised to include the wording:

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including - Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions."

The amended Indications for Use Statement is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

12. Please ensure that the revised IFU statement addresses all listed deficiencies.

The amended Indications for Use Statement is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

4 Indications for Use Statement

510(k) Number:

K101128.

Device Name:

BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A

Indications for Use:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w, which form electrostatic bonds with negatively-charged side-groups on biologicals).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against seasonal, pandemic, avian, swine and equine Influenza viruses including - Influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions.

Prescription Use _____ (21 CFR 801 Subpart D)	AND/OR	Over-The Counter Use ___X___ (21 CFR 801 Subpart C)

(PEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded and expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and body fluids.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

4 Labeling

CDRH Questions

13. You provided labeling that makes broad claims about the performance of the device against Influenza viruses. These claims include but are not limited to: “Inactivation of 99.99% of H1N1 Influenza,” “Pandemic and Seasonal Strains,” and “Inactivates Influenza A and B viruses.” These claims suggest that the subject device is capable of inactivation of all Influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim. Please provide labeling that only includes antiviral performance claims on virus strains that demonstrated a 4 $\log_{10}$ or greater reduction during in-vitro testing.

14. You provided labeling with the claim: “Kills Influenza Viruses on Contact.” This claim implies an instantaneous inactivation of Influenza which has not been substantiated. Please remove the claim: “Kills Influenza Viruses on Contact” from all labeling.

15. You provided labeling with the claim: “BioMask™ kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only.” This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file. Please revise the above labeling claim to accurately reflect the performance data.

16. You included the Indication for Use (IFU) statement in the labeling. Deficiencies 7 - 11 address the IFU related deficiencies. Please revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiencies 7 – 11.

17. The statement: “HOW IT WORKS: The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where Influenza viruses are inactivated” has not been supported by performance data. Please provide supporting data or revise/remove this claim.

18. Please include the following statement in the device labeling: “No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from Influenza infection."

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Please clarify if these claims are intended for the subject of this submission.

13. You provided labeling that makes broad claims about the performance of the device against Influenza viruses. These claims include but are not limited to: "Inactivation of 99.99% of H1N1 Influenza," "Pandemic and Seasonal Strains," and "Inactivates Influenza A and B viruses." These claims suggest that the subject device is capable of inactivation of all Influenza viral strains that fall into these categories and the FDA is not aware of testing methodologies that would support this claim. Please provide labeling that only includes antiviral performance claims on virus strains that demonstrated a 4 $\log_{10}$ or greater reduction during in-vitro testing.

The virucidal performance of the BioFriend™ BioMask™ surgical facemasks is discussed in detail in Questions 30-31, Section 7 of this Additional Information. The labeling has been revised to include only virucidal performance claims relating solely to the tested virus strains, and for those that demonstrated the necessary virucidal reduction during *in vitro* testing on 5 minutes contact with the surface of the mask.

The amended labeling is provided at the end of this section.

14. You provided labeling with the claim: "Kills Influenza Viruses on Contact." This claim implies an instantaneous inactivation of Influenza which has not been substantiated. Please remove the claim: "Kills Influenza Viruses on Contact" from all labeling.

The wording: "Kills Influenza Viruses on Contact" has been removed from the labeling.

The amended labeling is provided at the end of this section.

15. You provided labeling with the claim: "BioMask™ kills (inactivates) 99.99% of the following viruses within 5 minutes of contact with the surface of the face mask based on laboratory tests only." This statement implies that the performance claim was met in less than 5 minutes. Antiviral activity has been consistently demonstrated only at 5 minutes of contact with the device based on the data presented in this file. Please revise the above labeling claim to accurately reflect the performance data.

The revised wording: "Kills (inactivates) 99.99% of the following tested Influenza viruses on 5 minutes contact with the surface of the face mask, as tested in laboratories" is included in the labeling.

The amended labeling is provided at the end of this section.

16. You included the Indication for Use (IFU) statement in the labeling. Deficiencies 7 - 11 address the IFU related deficiencies. Please revise the IFU statement in the labeling, to be consistent with the revisions requested in deficiencies 7 – 11.

Labeling includes the revised Indications for Use Statement as amended within Section 3.

The amended labeling is provided at the end of this section.

17. The statement: "HOW IT WORKS: The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface of the mask and into the inner layers where Influenza viruses are inactivated" has not been supported by performance data. Please provide supporting data or revise/remove this claim.

The statement has been amended to: "HOW IT WORKS: The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the surface of the mask and into the inner layers where Influenza viruses are inactivated". This statement is supported by test data as discussed in Question 6, of this Additional Information.

The amended labeling is provided at the end of this section.

18. Please include the following statement in the device labeling: “No clinical studies have been conducted comparing the ability of a non-coated face mask and this face mask to protect the wearer from Influenza infection."

The statement: “No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection”, has been included in the revised Indications for Use Statement (Section 3).

The amended labeling is provided at the end of this section.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

The aforementioned claims contained within the online brochure are not intended for the subject of this submission and are associated to a different product that is intended for marketing outside of the USA. The Filligent website is currently undergoing modification and once this is complete users will be re-directed to region specific sub-domains. Users located in the United States will be re-directed to http://usa.filligent.com/ for product listing and information pertinent to the regulatory requirements of the United States. The website reference on the packaging refers readers to usa.filligent.com.

The amended labeling is provided at the end of this section.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Revised Labeling

The revised labeling for the BioFriend™ BioMask™ surgical facemask is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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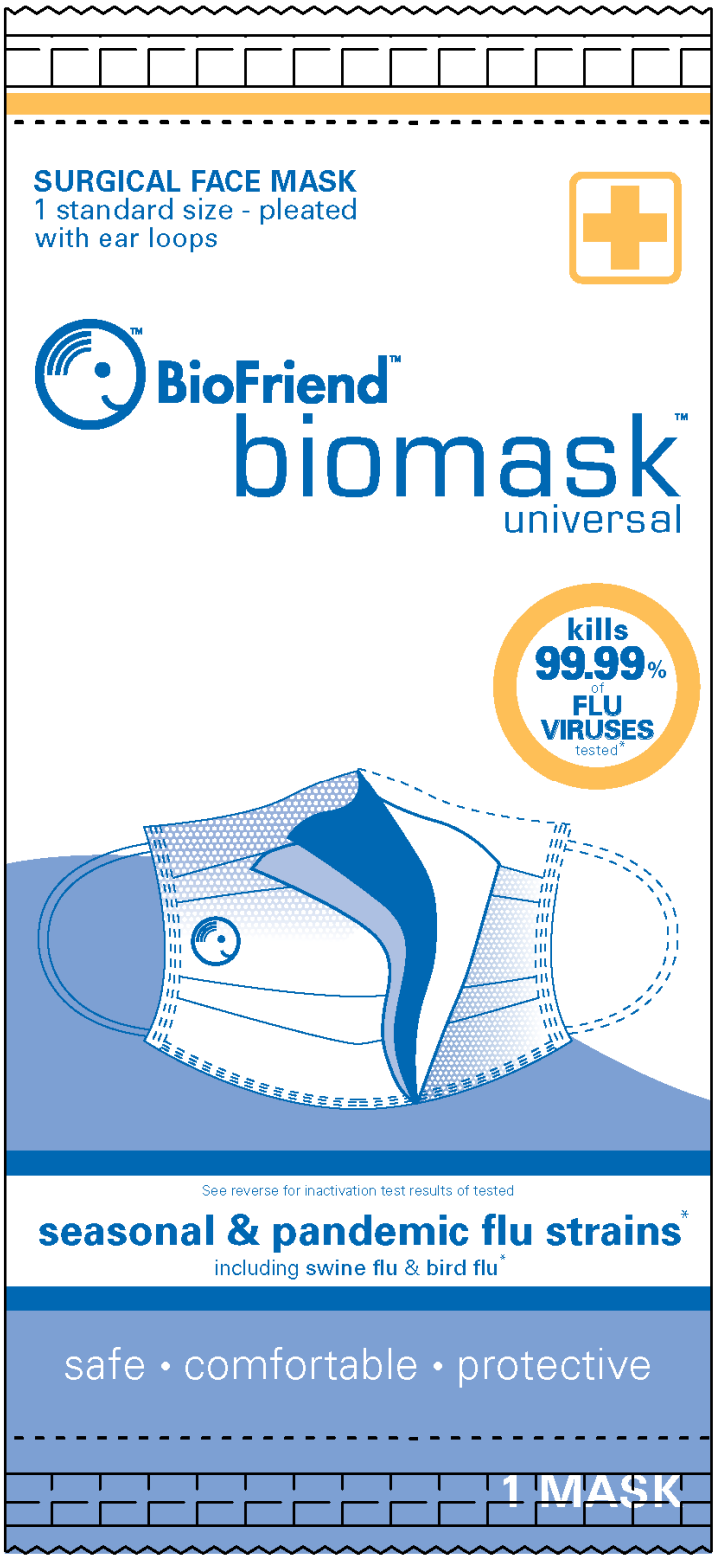
BioFriend™ BioMask™ Model: Universal BF-200-2001A

Bag - Principal Display Panel - Front



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Bag – Reverse

EXP: XX/XX/XXXX
LOT: XXXXXXX

BioFriend™
biomask™
universal

- Easy breathing
- Safe, smart & simple†
- Comfortable face-design

High Barrier
Surgical Face Mask
Meets ASTM F2100-07 Standard

inactivates **99.99%** of **H1N1** influenza virus tested*

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are killed (inactivated).

INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) **99.99% of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against seasonal, pandemic, avian, swine and equine influenza viruses including - influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and bodily fluids.

WARNINGS / CONTRA-INDICATIONS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- This mask does not contain natural latex.
- For use in medical settings only.
- For adult use only.

Part of an innovative range of products powered by BioFriend™ technology.

*Kills (inactivates) 99.99% of the following tested **influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal
Human (H1N1), A/Brisbane/59/2007
Human (H1N1), A/Wisconsin/10/98
Human (H1N1), A/New Jersey/8/76
Human (H3N2), A/Brisbane/10/2007
Human (H3N2), A/Wisconsin/67/2005
Human (H3N2), A/Victoria/3/75
Human, B/Brisbane/60/2008
Human, B/Florida/4/2006
Human, B/Lee/40
Pandemic
Pandemic H1N1, A/California/07/09
Human (H3N2), A/Hong Kong/8/68
Human (H2N2), A/2/JAPAN/305/57
Avian
Avian (H5N1), NIBRG-14
Duck (H5N2), A/Duck/PA/10218/84
Avian (H9N2), Turkey/Wis/66
Swine & Equine
Swine (H1N1), A/Swine/1976/31
Equine (H3N8), A/Equine/2/Miami/63
Other
Human (H1N1) A/PR/8/34

† when used as intended

Innovations by:
filligent
Website: usa.filligent.com
Email: contact.us@filligent.com

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Filligent (HK) Limited
7th floor, 69 Jervois Street, Sheung Wan, Hong Kong

BF-200-2001A/P-1359

4 897026 663847

Pragmatic • Scientific • Patented

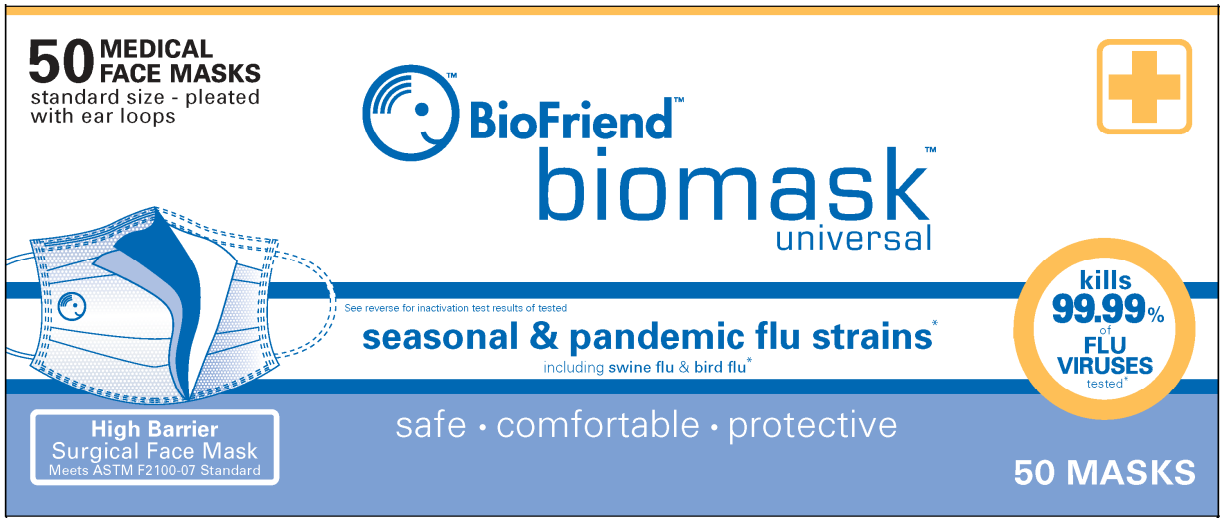
DISPOSABLE
SINGLE USE ONLY

20° +35°C 15% ~85%

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Complete Box

Box - Principal Display Panel – Front & Reverse

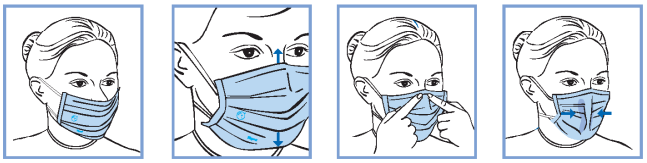


Box - Side Panel 1

BioFriend™
biomask™
universal

FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask.



1 Put loops around ears.

2 Adjust mask over nose & under chin.

3 Press forefingers down on both sides of nose.

4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

DISPOSABLE • SINGLE USE ONLY

HOW IT WORKS:

The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are killed (inactivated).

* **Kills (inactivates) 99.99%** of the following tested **influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal	Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Victoria/3/75 Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40
Pandemic	Pandemic H1N1, A/California/07/09 Human (H3N2), A/Hong Kong/8/68 Human (H2N2), A/2/JAPAN/305/57
Avian	Avian (H5N1), NIBRG-14 Duck (H5N2), A/Duck/PA/10218/84 Avian (H9N2), Turkey/Wis/66
Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

Box – Side Panel 2

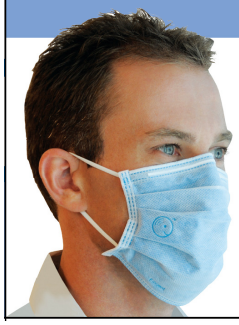
BioFriend™
biomask™
universal

DISPOSABLE
SINGLE USE ONLY

- Easy breathing
- Safe, smart & simple†
- Comfortable face-design

inactivates **99.99%** of **H1N1** influenza virus tested*

Part of an innovative range of products powered by BioFriend™ technology.



INDICATIONS FOR USE:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) **99.99% of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against seasonal, pandemic, avian, swine and equine influenza viruses including - influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/ California/07/09, A/Brisbane/59/2007, A/Wisconsin/ 10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/ 305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/ PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/ Miami/63); and influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and bodily fluids.

WARNINGS / CONTRA-INDICATIONS

- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- This mask does not contain natural latex.
- For use in medical settings only.
- For adult use only.

† when used as intended

Box – Lid

Box – Bottom

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-3013A

Bag - Principal Display Panel - Front

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

BioFriend™ BioMask™ Model: Universal BF-200-3013A

Bag - Reverse

EXP: XX/XX/XXXX
LOT: XXXXXXX

High Barrier
Surgical Face Mask
Meets ASTM F2100-07 Standard

BioFriend™
biomask™
premium

- Easy breathing
- Safe, smart & simple†
- Comfortable face-design

inactivates
99.99% of
H1N1
influenza virus
tested*

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are killed (inactivated).

INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on biologicals).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) **99.99% of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against seasonal, pandemic, avian, swine and equine influenza viruses including - influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/ 10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/ 67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/JAPAN/ 305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (Avian Influenza H9N2), H5N2 (A/Duck/ PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Brisbane/60/ 2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material. These devices also help to protect the wearer from splash and spray of blood and bodily fluids.

Innovations by:
filligent™ creating global health choices
Pragmatic • Scientific • Patented

***Kills (inactivates) 99.99%** of the following tested **influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal	Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Victoria/3/75 Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40
Pandemic	**Pandemic H1N1, A/California/07/09** Human (H3N2), A/Hong Kong/8/68 Human (H2N2), A/2/JAPAN/305/57
Avian	Avian (H5N1), NIBRG-14 Duck (H5N2), A/Duck/PA/10218/84 Avian (H9N2), Turkey/Wis/66
Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

WARNINGS / CONTRA-INDICATIONS
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- This mask does not contain natural latex.
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Part of an innovative range of products powered by BioFriend™ technology.

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Filligent (HK) Limited
7th floor, 69 Jervois Street,
Sheung Wan, Hong Kong

REF BF-200-3013A/P-1360

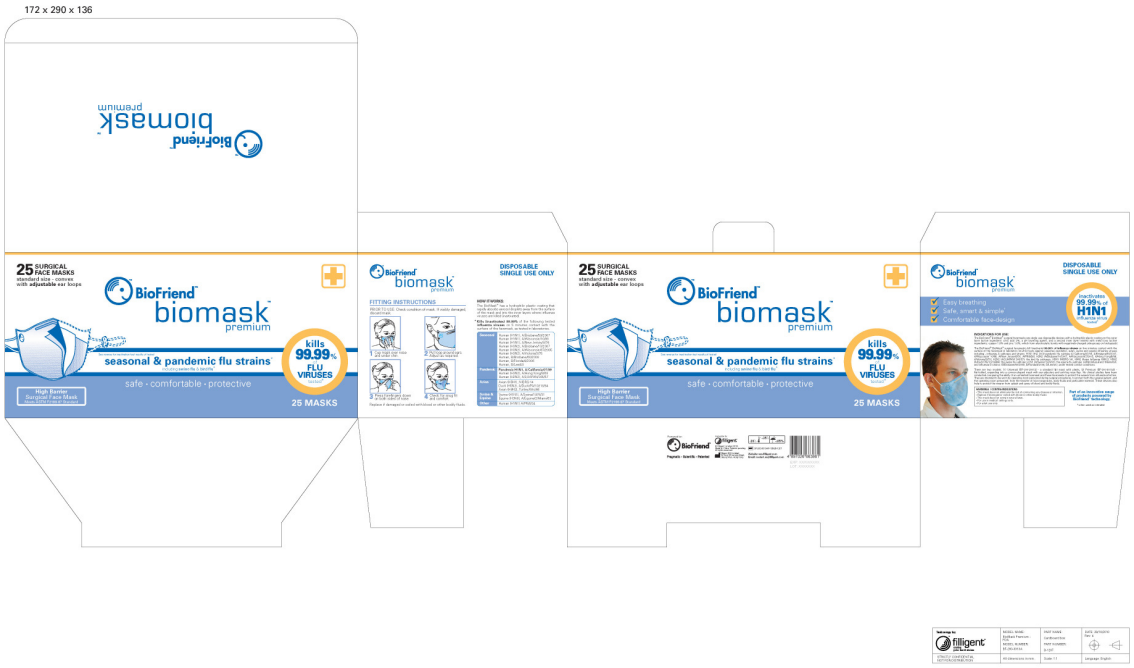
4 897026 663854

DISPOSABLE • SINGLE USE ONLY

-20°c +35°c <85%

BioFriend™ BioMask™ Model: Universal BF-200-3013A

Complete Box



Box - Principal Display Panel – Front & Reverse

Box - Side Panel 1

BioFriend™
biomask™
premium

DISPOSABLE SINGLE USE ONLY

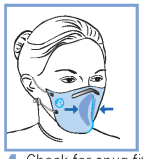
FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask.

1 Cup mask over nose and under chin.

2 Put loop around ears. Adjust as required.

3 Press forefingers down on both sides of nose.



4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are killed (inactivated).

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Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

Box – Side Panel 2

BioFriend™
biomask™
premium

DISPOSABLE SINGLE USE ONLY

- Easy breathing
- Safe, smart & simple†
- Comfortable face-design

inactivates **99.99%** of **H1N1** influenza virus tested†

INDICATIONS FOR USE:
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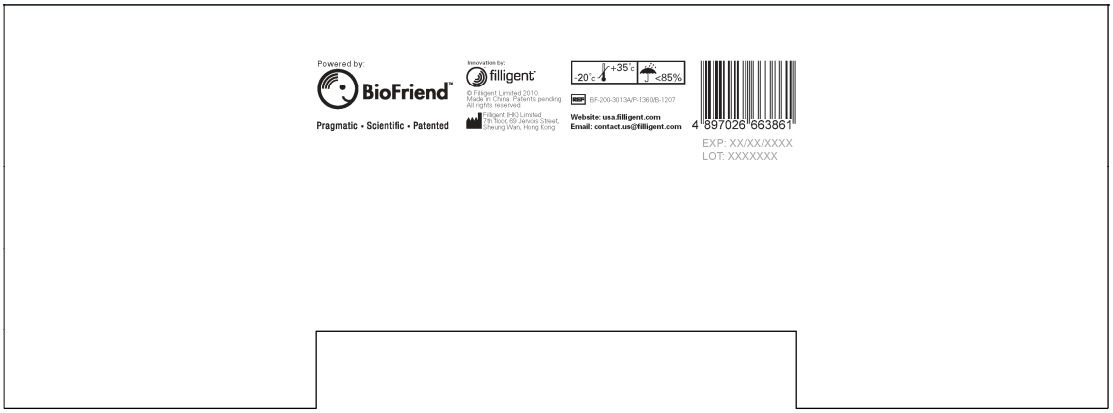
Part of an innovative range of products powered by BioFriend™ technology.

† when used as intended

Box – Lid

Box – Bottom



5 Shelf-Life

CDRH Questions

20. You did not indicate the shelf life of the subject device. Please indicate the shelf life of the subject device.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

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Ingestion	Wash out mouth with water. Drink plenty of water.
Advice for the doctor	Symptomatic treatment
Further information	See section 16 of MSDS

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents	Waterspray, foam, powder, carbon dioxide.
Restrictions	No restrictions.
Fire/explosion hazard	None
Main combustion gas	Carbon, nitrogen and sulfur oxides
Personal protection	Self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal protection	Gloves, respiratory protection.
Environmental precautions	No special precautions
Spillage procedure	Damp down. Avoid dust. Scoop into marked containers for disposal as chemical waste. Flush residues away with water.

7. HANDLING AND STORAGE

Handling

Occupational hygiene	Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Storage

Fire precautions	No special measures required
Storage facilities	Store in a cool, dry area with adequate ventilation
Segregation	Keep away from alkali.
Storage conditions	Keep containers closed. Sensitive to heat over 40 °C.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits	None. Ensure adequate ventilation

Exposure Controls

Occupational exposure controls	
General Personal Protection	Gloves, respiratory protection.
Hand protection	Chemical resistant protective gloves (EN 374). Recommended: permeation time >30 min. (level 2), material e.g. butyl or neopren. Observe glove manufacturers instructions.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Appearance	
Form	Powder
Colour	Blue

(b) (4)

[redacted]

Odour	None		
Important health safety and environmental information			
pH	5 - 5.5		20 g/l
Boiling point	Not applicable		
Flash point	Not applicable		
Oxidising properties	None		
Solubility in water	80 g/l		at 30 °C
	80 g/l		90 °C
Other information			
Melting point	> 250 °C		
Bulk density	657 kg/m3		
Thermal decomposition	230 °C		
Ignition temperature	480 °C	BAM	

10. STABILITY AND REACTIVITY

Conditions to avoid	None.
Materials to avoid	None
Hazardous decomposition products	None under normal storage conditions

11. TOXICOLOGICAL INFORMATION

Acute toxicity			
- LD50 oral	> 2000 mg/kg	Rat	
Primary irritation			
(Skin)	Non-irritant	Rabbit	
(Eye)	Non-irritant	Rabbit	
Skin sensitisation	Sensitizing	Guinea Pig	OECD 406
Adverse effects in man	See 16 in MSDS		
Additional information			

12. ECOLOGICAL INFORMATION

Ecotoxicity

Bacterial toxicity				
	IC50	> 300 mg/l	3 hour	
Fish toxicity	LC0	100 mg/l	48 hour Golden orfe	
	LC50	> 100 mg/l		
Summary		Not toxic or harmful to aquatic organisms		

Persistance and degradability

Bioelimination	10-25%, DOC Analysis.	OECD 302B
Summary	Poorly eliminated by adsorption on effluent treatment sludge	
Behaviour in treatment plants	No inhibition. No nitrification inhibition known	

Additional Ecology Data

Phosphorus content	0 %	
Organohalogen content	0 %	
Metal content	2.04 %	Copper as organo-metal complex

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[redacted]

Tested material	Standardised product
Additional information	

13. DISPOSAL CONSIDERATIONS

Product disposal	Incineration, landfill. Observe local regulations.
Contaminated packaging	Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

KEEP AWAY FROM FOODSTUFFS

Not classified as dangerous goods

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Symbol and classification	Xi : Irritant
R-Phrases	R43 : May cause sensitisation by skin contact
S-Phrases	S22 : Do not breathe dust
	S24 : Avoid contact with skin
	S37 : Wear suitable gloves
Contains	C.I. Reactive Blue 21
EU Guideline	99/45

16. OTHER INFORMATION

Cases of respiratory sensitisation have been observed with reactive dyes.

Care should be taken to avoid inhalation.

Should an individual become sensitized a physician should be consulted and all contact with reactive dyes must cease immediately.

List of relevant R-phrases (Section 2)

R43 : May cause sensitisation by skin contact

Recommended restrictions on use

Huntsman textile, paper and leather dyes and chemicals are technical grade and unless otherwise stated or agreed are recommended only for industrial use in applications involving the pretreatment dyeing or finishing of textiles, paper or leather. Other intended uses including their use in consumer products governed by specific legislation or standards should be referred to the manufacturer. The data contained in the SDS apply only to Huntsman products sold under the stated trade names. Technical information in support will be provided by Huntsman at the request of competent authorities.

member of ETAD

MSDS Changes	15. REGULATORY INFORMATION
	S-Phrases

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Canadian Centre for Occupational Health and Safety

CCOHS

RTECS Registry of Toxic Effects of Chemical Substances®

Data source: Symyx Software Inc.

Record Contents

Format: All Sections

- ☑ Chemical Identification
- ☑ Acute Toxicity Data
- ☑ Other Multiple Dose Toxicity Data
- ☑ Reproductive Data
- ☑ Occupational Exposure Limits
- ☑ Status in U.S.

REFRESH RECORD

CHEMICAL IDENTIFICATION

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

(b)(4) [redacted]

HEALTH HAZARD DATA

ACUTE TOXICITY DATA

Type of Test	Route of Exposure	Species Observed	Dose Data	Toxic Effects	Reference
LD50 - Lethal dose, 50 percent kill	Oral	Rodent - rat	501 mg/kg	Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold	(b)(4) [redacted]
LD50 - Lethal dose, 50 percent kill	Intraperitoneal	Rodent - rat	14700 ug/kg	Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold	
LD50 - Lethal dose, 50 percent kill	Subcutaneous	Rodent - rat	350 mg/kg	Musculoskeletal - joints Tumorigenic - active as anti-cancer agent Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation	

(b)(4) [redacted]

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LD50 - Lethal dose, 50 percent kill	Intravenous	Rodent - rat	17100 ug/kg	Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold
LD50 - Lethal dose, 50 percent kill	Oral	Rodent - mouse	196 mg/kg	Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold
LD50 - Lethal dose, 50 percent kill	Intraperitoneal	Rodent - mouse	2500 ug/kg	Details of toxic effects not reported other than lethal dose value
LD50 - Lethal dose, 50 percent kill	Intravenous	Rodent - mouse	20 mg/kg	Behavioral - somnolence (general depressed activity) Behavioral - convulsions or effect on seizure threshold

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(b)(4) [redacted]

LDLo - Lowest published lethal dose	Oral	Rodent - rabbit	250 mg/kg	Details of toxic effects not reported other than lethal dose value
LD50 - Lethal dose, 50 percent kill	Oral	Rodent - rat	595 mg/kg	Details of toxic effects not reported other than lethal dose value

OTHER MULTIPLE DOSE TOXICITY DATA

Type of Test	Route of Exposure	Species Observed	Dose Data	Toxic Effects
TDLo - Lowest published toxic dose	Oral	Rodent - rat	23750 mg/kg/42W (continuous)	Lungs, Thorax, Respiration - fibrosis, focal (pneumoconiosis Liver - other changes Kidney/ Ureter/Bladder - other changes

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

TDLo - Lowest published toxic dose	Intraperitoneal	Rodent - rat	56 mg/kg/7D (intermittent)	Blood - other changes Nutritional and Gross Metabolic - changes in metals, not otherwise specified Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - other Enzymes
TDLo - Lowest published toxic dose	Oral	Primate - monkey	3360 mg/kg/24W (continuous)	Liver - other changes Related to Chronic Data - death
TDLo - Lowest published toxic dose	Oral	Rodent - rabbit	21840 mg/kg/2Y (continuous)	Brain and Coverings - other degenerative changes Liver - other changes Related to Chronic Data - death

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

TDLo - Lowest published toxic dose	Oral	Rodent - rabbit	17500 mg/kg/50W (continuous)	Liver - hepatitis, fibrous (cirrhosis, post-necrotic scarring) Liver - jaundice, other or unclassified Related to Chronic Data - death
TDLo - Lowest published toxic dose	Subcutaneous	Rodent - rabbit	100 mg/kg/1W (intermittent)	Lungs, Thorax, or Respiration - chronic pulmonary edema Liver - hepatitis (hepatocellular necrosis), zonal Related to Chronic Data - death
TDLo - Lowest published toxic dose	Subcutaneous	Mammal - species unspecified	23333 ug/kg/26W (intermittent)	Liver - changes in liver weight Kidney/Ureter/Bladder - changes in tubules (including acute renal failure, acute tubular necrosis) Endocrine - changes in spleen weight

REPRODUCTIVE DATA

(b)(4) [redacted]

(b)(4) [redacted]

Type of Test	Route of Exposure	Species Observed	Dose Data	Sex/ Duration	Toxic Effects
TDLo - Lowest published toxic dose	Subcutaneous	Rodent - rat	40 mg/ kg	female 7-10 day(s) after conception	Reproductive - Fertility - other measures of fertility

(b)(4) [redacted]

OCCUPATIONAL EXPOSURE LIMITS

OEL-ARAB Republic of Egypt: TWA 0.1 mg(Cu)/m3 (fume), JAN1993

OEL-AUSTRALIA: TWA 0.2 mg(Cu)/m3 (fume), JAN1993

OEL-AUSTRALIA: TWA 1 mg(Cu)/m3 (dust), JAN1993

OEL-FINLAND: TWA 0.2 mg(Cu)/m3 (fume), JAN1993

OEL-FINLAND: TWA 1 mg(Cu)/m3 (dust), JAN1993

OEL-HUNGARY: TWA 1 mg(Cu)/m3, STEL 4 mg(Cu)/m3, SEP2000

OEL-INDIA: TWA 0.2 mg(Cu)/m3 (fume), JAN1993

OEL-RUSSIA: STEL 0.5 ppm (1 mg(Cu)/m3) (dust), JUN2003

OEL-SWEDEN: TWA 1 mg(Cu)/m3;TWA 0.2 mg(Cu)/m3 (resp. dust), JUN2005

OEL-SWITZERLAND: MAK-W 0.1 mg(Cu)/m3,KZG-W 0.2 mg(Cu)/m3, DEC2006

OEL-THAILAND: TWA 1 mg(Cu)/m3, JAN1993

OEL-THAILAND: TWA 0.1 mg(Cu)/m3 (fume), JAN1993

STATUS IN U.S.

EPA TSCA Section 8(b) CHEMICAL INVENTORY

(b)(4) [redacted]

(b)(4)

END OF RECORD

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Mail: 135 Hunter Street East, Hamilton Ontario L8N 1M5

(b)(4)

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Copper fume (as Cu)

IDLH Documentation

CAS number: 1317–38–0 (CuO)

NIOSH REL: 0.1 mg/m^3 TWA

Current OSHA PEL: 0.1 mg/m^3 TWA

1989 OSHA PEL: Same as current PEL

1993-1994 ACGIH TLV: 0.2 mg/m^3 TWA

Description of Substance: Finely divided black particulate dispersed in air.

LEL: . . Noncombustible Solids

Original (SCP) IDLH*: No Evidence [*Note: "Effective" IDLH = 200 mg Cu/m^3 -- see discussion below.]

Basis for original (SCP) IDLH: There is no evidence that an acute exposure to a high concentration of copper fume could impede escape within 30 minutes. Browning [1969] noted that there is little evidence that copper presents a serious industrial hazard, either from acute or chronic poisoning. For this draft technical standard, therefore, respirators have been selected on the basis of the assigned protection factor afforded by each device up to 2,000 × the OSHA PEL of 0.1 mg Cu/m^3 (i.e., 200 mg Cu/m^3); only the "most protective" respirators are permitted for use in concentrations exceeding 200 mg Cu/m^3.

Short-term exposure guidelines: None developed

ACUTE TOXICITY DATA

Animal data: None relevant for use in determining the revised IDLH.

Human data: Exposure to copper fume causes upper respiratory tract irritation, metallic taste, nausea, and metal fume fever. It has been reported that no ill effects resulted from exposures to copper fumes at concentrations up to 0.4 mg Cu/m^3 [Luxon 1972] and that there is little evidence that copper presents a serious industrial hazard, either from acute of chronic poisoning [Browning 1969].

Revised IDLH: 100 mg Cu/m^3

Basis for revised IDLH: The revised IDLH for copper fume is 100 mg Cu/m^3 based on an analogy to copper dusts and mists which have a revised IDLH of 100 mg Cu/m^3. This may be a conservative value due to the lack of relevant acute toxicity data for workers exposed to concentrations above 100 mg Cu/m^3.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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REFERENCES:

1. Browning E [1969]. Toxicity of industrial metals. 2nd ed. New York, NY: Appleton-Century-Crofts, p. 148.

2. Luxon SG [1972]. Letter to ACGIH TLV Committee. London, England: H.M. Factory Inspectorate, Industrial Hygiene Unit, August 1, 1972.

Go back to the Documentation for Immediately Dangerous To Life or Health Concentrations (IDLHs)

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7 Antiviral Performance Testing

CDRH Questions

30. You have provided antiviral performance testing that shows that an average log reduction of 4 logs or more was not achieved against Influenza B/Brisbane/60/2006. Only 1 of 2 studies showed borderline

(b)(4)

[redacted]

and Influenza A/Swine/1976/31.

31. Please discuss the variable and borderline anti-Influenza performance. Please explain whether this variable performance may be related to the wide acceptance criteria for the BioMask antimicrobial agent components, especially citric acid.

32. Please identify how many lots of product were used in the antiviral performance studies. FDA is concerned that the broad antiviral component specifications may contribute to the variable device performance demonstrated.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

30. You have provided antiviral performance testing that shows that an average log reduction of 4 logs or more was not achieved against Influenza B/Brisbane/60/2006. Only 1 of 2 studies

(b)(4)

[redacted]

the inadequate performance against Influenza B/Brisbane/60/2006 and Influenza A/Swine/1976/31.

Based on the amended and re-issued Microbiotest test results relating to confidence intervals, and the performance criteria described below, the BioFriend™ BioMask™ surgical facemasks showed acceptable virucidal performance against Influenza B/Brisbane/60/2006 and Influenza A/Swine/1976/31.

Results:

(b)(4)

[redacted]

The results showing the virucidal performance of the BioFriend™ BioMask™ surgical facemasks against 18 virus strains of Influenza A and B - Summary of Virucidal Performance of the BioFriend™ BioMask™ Surgical Facemask against Influenza – Average Log-Reduction of Virus after 5 Minutes Contact - are summarized in Table 33.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Table 33 Summary of Virucidal Performance of the BioFriend™ BioMask™ Surgical Facemask against Influenza – Average Log-Reduction of Virus after 5 Minutes Contact.

Subtype	Isolate	Initial Viral Load (Log_{10} $TCID_{50}$)	Average Log Reduction ±95% CI [1]
H1N1	(b)(4) [redacted]		
H2N2			
H3N2			
H5N1			
H5N2			
H9N2			
H3N8			
B			

[1] Derived from three replicate runs.

* No virus detected in 3 out of 3 replicates tested.

† No virus detected in 1-2 of 3 replicates tested.

When no residual virus was detected, the Poisson distribution was used to statistically estimate the minimum detectable virus level based on the assay sensitivity and the sample volume used. This theoretical minimum detectable virus level was then used to calculate the log_{10} reduction. This log value therefore represents the most conservative estimate of virucidal efficacy.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Discussion:

Determination of acceptable performance.

The performance criteria used for determining successful virucidal performance of the devices are as follows: The BioFriend™ BioMask™ surgical facemasks were considered to demonstrate "unequivocal"

(b)(4)

[redacted]

represents the most conservative estimate of virucidal efficacy.

Performance of Influenza B/Brisbane/60/2008.

No virus was detected following the 5 minute contact time for Influenza B/Brisbane/60/2008 on all three

(b)(4)

[redacted]

detected, was considered acceptable performance in the circumstances.

It should be noted that copper and zinc were observed to cause cytotoxicity in the $TCID_{50}$ viral infectivity

(b)(4)

[redacted]

Performance of Influenza A/Swine/1976/31.

(b)(4)

[redacted]

Conclusion:

Based on the amended and re-issued test results and the above performance criteria, 17 out of the 18 strains tested show either "unequivocal" or "acceptable" virucidal performance against tested strains of

(b)(4)

[redacted]

Test Reports:

The amended and re-issued full test reports are appended to the end of this section:

(b)(4)

[redacted]

(b)(4) Deficiencies and Responses to Deficiencies

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K101128/S001

FDA CDRH DMC

JUN 7 2010

Received

K - LeC

June 4, 2010

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information - 510(k) Premarket Notification – K101128

This letter constitutes Filligent (HK) Limited's response to CDRH's request for additional information, which was dated and received by email on Wednesday, April 28, 2010. Each request is listed in the following pages, together with our response.

We believe that this response will provide adequate information to reach a determination of substantial equivalence. Nevertheless, if you require additional information, please do not hesitate to contact us at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact CDRH at CDRHOD@DMC@DMCSTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

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June 4, 2010

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information - 510(k) Premarket Notification – K101128

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7th Floor, 69 Jervois Street

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Telephone: +852 2542 2400

Fascimile: +852 2542 2411

Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Question 6. Please provide the levels of citric acid, copper and zinc in your devices by ugm or mgm per unit of area such as cm^2 for your devices

See response to Question 7.

(b)(4) Deficiencies and Responses to Deficiencies

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Figure 1 Major Dimensions of the BioFriend™ BioMask™ Universal BF-200-2001

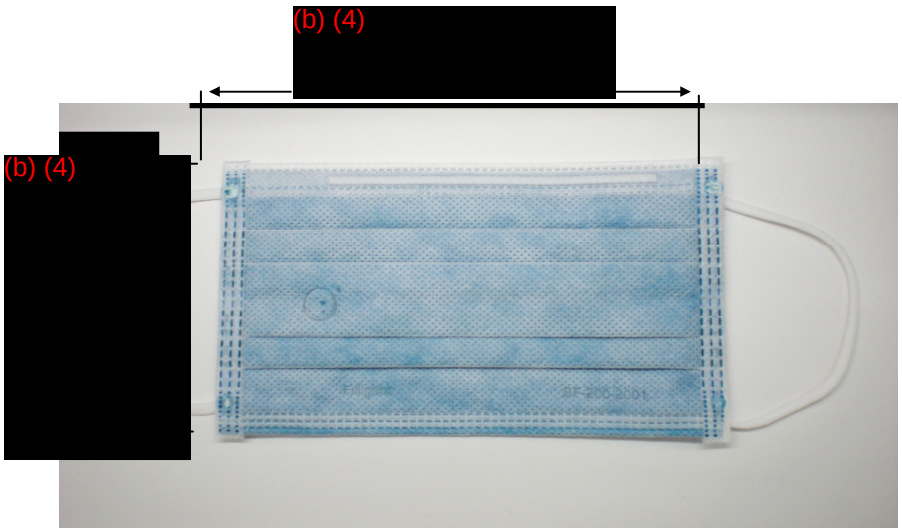

Figure 2 Major Dimensions of the BioFriend™ BioMask™ Premium BF-200-3013

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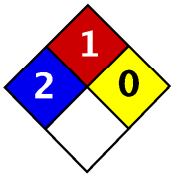
Attachment 2-A: Citric Acid MSDS



Health	2
Fire	1
Reactivity	0
Personal Protection	E

Material Safety Data Sheet
Citric acid MSDS

Section 1: Chemical Product and Company Identification

Product Name: Citric acid

Catalog Codes: SLC5449, SLC2665, SLC4453, SLC1660, SLC3451

CAS#: 77-92-9

RTECS: GE7350000

TSCA: TSCA 8(b) inventory: Citric acid

CI#: Not available.

Synonym: 2-Hydroxy-1,2,3-propanetricarboxylic acid

Chemical Name: Citric Acid

Chemical Formula: C6H8O7

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Citric acid	77-92-9	100

Toxicological Data on Ingredients: Citric acid: ORAL (LD50): Acute: 5040 mg/kg [Mouse]. 3000 mg/kg [Rat].

Section 3: Hazards Identification

Potential Acute Health Effects:
Hazardous in case of eye contact (irritant), of inhalation (lung irritant). Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion. The amount of tissue damage depends on length of contact. Eye contact can result in corneal damage or blindness. Skin contact can produce inflammation and blistering. Severe over-exposure can produce lung damage, choking, unconsciousness or death.

Potential Chronic Health Effects:
Slightly hazardous in case of skin contact (sensitizer).
CARCINOGENIC EFFECTS: Not available.
MUTAGENIC EFFECTS: Not available.
TERATOGENIC EFFECTS: Not available.
DEVELOPMENTAL TOXICITY: Not available.
The substance may be toxic to teeth.
Repeated or prolonged exposure to the substance can produce target organs damage. Repeated exposure of the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Attachment 2-A: Citric Acid MSDS

eyes to a low level of dust can produce eye irritation. Repeated skin exposure can produce local skin destruction, or dermatitis. Repeated inhalation of dust can produce varying degree of respiratory irritation or lung damage.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Skin Contact:
In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact:
Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: 1010°C (1850°F)

Flash Points: Not available.

Flammable Limits: LOWER: 0.28 Kg/M3 (Dust) UPPER: 2.29 Kg/M3 (Dust)

Products of Combustion: These products are carbon oxides (CO, CO2).

Fire Hazards in Presence of Various Substances:
Slightly flammable to flammable in presence of heat.
Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Slightly explosive in presence of open flames and sparks.
Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Attachment 2-A: Citric Acid MSDS

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Eliminate all ignition sources. Call for assistance on disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, reducing agents, metals, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:
Safety glasses. Lab coat. Gloves (impervious). Dust respirator. Be sure to use an approved/certified respirator or equivalent. The dust respirator should be used for conditions where exposure has exceeded recommended exposure limits, dust is apparent, and engineering controls(adequate ventilation) are not feasible.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:
No exposure guidelines have been established.
ACGIH, NIOSH and OSHA have not developed exposure limits for this product.
The exposure limits given below are for particulates not otherwise classified:
ACGIH: 10 mg/m3 TWA (Total Inhalable fraction); 3 mg/m3 TWA (Respirable fraction)
OSHA: 15 mg/m3 TWA (Total dust); 5 mg/m3 TWA (Respirable Fraction)

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Crystalline powde)

Odor: Odorless.

Taste: Acid. (Strong.)

Molecular Weight: 192.13 g/mole

Color: Not available.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Attachment 2-A: Citric Acid MSDS

pH (1% soln/water): Not available.

Boiling Point: Decomposes.

Melting Point: 153°C (307.4°F)

Critical Temperature: Not available.

Specific Gravity: 1.665 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: The product is more soluble in water; log(oil/water) = -1.7

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water, diethyl ether.

Solubility:
Soluble in cold water, hot water, diethyl ether.
Insoluble in benzene.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents, reducing agents, metals, alkalis.

Corrosivity:
Corrosive in presence of aluminum, of zinc, of copper.
Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Incompatible with oxidizing agents, potassium tartrate, alkali, alkaline earth carbonates and bicarbonates, acetates, and sulfides, metal nitrates

Special Remarks on Corrosivity: Will corrode copper, zinc, aluminum and their alloys.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 3000 mg/kg [Rat].

Chronic Effects on Humans: May cause damage to the following organs: teeth.

Other Toxic Effects on Humans:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Attachment 2-A: Citric Acid MSDS

Hazardous in case of inhalation (lung irritant).
Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion.

Special Remarks on Toxicity to Animals: LDL[Rabbit] - Route: oral; Dose: 7000mg/kg

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects:
Skin: Causes mild to moderate skin irritation. May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material.
Eyes: Causes moderate to severe eye irritation and possible injury.
Ingestion: May cause gastrointestinal (digestive) tract irritation with nausea, vomiting, diarrhea. Excessive intake may cause erosion of teeth and hypocalcemia (calcium deficiency in blood). May affect behavior/central nervous system (tremor, convulsions, muscle contraction or spasticity).
Inhalation: Causes moderate respiratory tract and mucous membrane irritation.
Chronic Potential Health Effects:
Frequent intake of citrated beverages may cause erosion of dental enamel and irritation of mucous membranes.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Citric acid

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): CLASS E: Corrosive solid.

DSCL (EEC):

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Attachment 2-A: Citric Acid MSDS

R36/37/38- Irritating to eyes,
respiratory system and skin.
S26- In case of contact with eyes, rinse
immediately with plenty of water and seek
medical advice.
S37/39- Wear suitable gloves and eye/face
protection.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: e

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves (impervious).
Lab coat.
Dust respirator. Be sure to use an
approved/certified respirator or
equivalent. Wear appropriate respirator
when ventilation is inadequate.
Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 04:56 PM

Last Updated: 11/06/2008 12:00 PM

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall ScienceLab.com be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if ScienceLab.com has been advised of the possibility of such damages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

(b) (4)

[redacted]

Potential Health Effects

Inhalation:
Causes irritation to respiratory tract, symptoms may include coughing, sore throat, and shortness of breath. May result in ulceration and perforation of respiratory tract. When heated, this compound may give off copper fume, which can cause symptoms similar to the common cold, including chills and stuffiness of the head.
Ingestion:
May cause burning pain in the mouth, esophagus, and stomach. Hemorrhagic gastritis, nausea, vomiting, abdominal pain, metallic taste, and diarrhea may occur. If vomiting does not occur immediately systemic copper poisoning may occur. Symptoms may include capillary damage, headache, cold sweat, weak pulse, kidney and liver damage, central nervous excitation followed by depression, jaundice, convulsions, blood effects, paralysis and coma. Death may occur from shock or renal failure.
Skin Contact:
May cause irritation with redness and pain.
Eye Contact:
Corrosive. May cause irritation, redness, pain, blurred vision, discoloration, and damage.
Chronic Exposure:
Prolonged or repeated skin exposure may cause dermatitis. Prolonged or repeated exposure to dusts of copper salts may cause discoloration of the skin or hair, blood and liver damage, ulceration and perforation of the nasal septum, runny nose, metallic taste, and atrophic changes and irritation of the mucous membranes.
Aggravation of Pre-existing Conditions:
Persons with pre-existing skin disorders, impaired liver, kidney, or pulmonary function, glucose 6-phosphate-dehydrogenase deficiency, or pre-existing Wilson's disease may be more susceptible to the effects of this material.

4. First Aid Measures

Inhalation:
Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
Ingestion:
Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. Call a physician.
Skin Contact:
In case of contact, wipe off excess material from skin then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Call a physician.
Eye Contact:
Immediately flush eyes with gentle but large stream of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Call a physician immediately.

5. Fire Fighting Measures

Fire:
Not considered to be a fire hazard. May form combustible fumes upon decomposition which may increase the flammability of a fire.
Explosion:
Reactions with incompatibles may pose an explosion hazard.
Fire Extinguishing Media:
Use any means suitable for extinguishing surrounding fire. Water spray may be used to keep fire exposed containers cool.
Special Information:
In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with

(b) (4)

full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

US Regulations (CERCLA) require reporting spills and releases to soil, water and air in excess of reportable quantities. The toll free number for the US Coast Guard National Response Center is (800) 424-8802. Ventilate area of leak or spill. Keep unnecessary and unprotected people away from area of spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Isolate from incompatible substances. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:
-OSHA Permissible Exposure Limit (PEL):
1 mg/m3 (TWA) for copper dusts & mists as Cu
-ACGIH Threshold Limit Value (TLV):
1 mg/m3 (TWA) for copper dusts & mists as Cu
Ventilation System:
A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.
Personal Respirators (NIOSH Approved):
If the exposure limit is exceeded and engineering controls are not feasible, a half facepiece particulate respirator (NIOSH type N95 or better filters) may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest.. A full-face piece particulate respirator (NIOSH type N100 filters) may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency, or respirator supplier, whichever is lowest. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.
Skin Protection:
Wear protective gloves and clean body-covering clothing.
Eye Protection:
Use chemical safety goggles and/or full face shield where dusting or splashing of solutions is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:
Dark green powder.
Odor:
Slight acetic acid odor.
Solubility:

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7.2 g/100 cc cold water; 20 g/100 cc hot water.
Density:
1.88
pH:
No information found.
% Volatiles by volume @ 21C (70F):
0
Boiling Point:
240C (464F) Decomposes.
Melting Point:
115C (239F)
Vapor Density (Air=1):
No information found.
Vapor Pressure (mm Hg):
No information found.
Evaporation Rate (BuAc=1):
No information found.

10. Stability and Reactivity

Stability:
Stable under ordinary conditions of use and storage.
Hazardous Decomposition Products:
May produce oxides of carbon and the contained metal.
Hazardous Polymerization:
Will not occur.
Incompatibilities:
Sodium hypobromite, acetylene, hydrazine, and nitromethane.
Conditions to Avoid:
Incompatibles.

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12. Ecological Information

Environmental Fate:
This material is expected to significantly bioaccumulate. This material has an experimentally-determined bioconcentration factor (BCF) of greater than 100. Bioaccumulation data for copper.
Environmental Toxicity:
This material is expected to be very toxic to aquatic life. The LC50/96-hour values for fish are less than 1 mg/l. The IC50/72-hour values for algae are less than 1 mg/l. Toxicity data for copper.

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[redacted]

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

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[redacted]

(b) (4)

(b) (4)

16. Other Information

NFPA Ratings: Health: **2** Flammability: **0** Reactivity: **0**
Label Hazard Warning:
DANGER! CAUSES EYE BURNS. HARMFUL IF SWALLOWED. CAUSES IRRITATION TO SKIN AND RESPIRATORY TRACT.
Label Precautions:
Do not get in eyes.
Avoid breathing dust.
Keep container closed.
Use with adequate ventilation.
Wash thoroughly after handling.
Avoid contact with skin and clothing.
Label First Aid:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. In case of skin contact, wipe any excess material off skin and then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. In all cases, get medical attention.
Product Use:
Laboratory Reagent.
Revision Information:
No Changes.
Disclaimer:
****
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(b) (4)

[redacted]

THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT BAKER, INC. WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

****

Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

(b) (4)

[redacted]

Ingestion	Wash out mouth with water. Drink plenty of water.
Advice for the doctor	Symptomatic treatment
Further information	See section 16 of MSDS

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents	Waterspray, foam, powder, carbon dioxide.
Restrictions	No restrictions.
Fire/explosion hazard	None
Main combustion gas	Carbon, nitrogen and sulfur oxides
Personal protection	Self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal protection	Gloves, respiratory protection.
Environmental precautions	No special precautions
Spillage procedure	Damp down. Avoid dust. Scoop into marked containers for disposal as chemical waste. Flush residues away with water.

7. HANDLING AND STORAGE

Handling

Occupational hygiene	Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Storage

Fire precautions	No special measures required
Storage facilities	Store in a cool, dry area with adequate ventilation
Segregation	Keep away from alkali.
Storage conditions	Keep containers closed. Sensitive to heat over 40 °C.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits	None. Ensure adequate ventilation

Exposure Controls

Occupational exposure controls	
General Personal Protection	Gloves, respiratory protection.
Hand protection	Chemical resistant protective gloves (EN 374). Recommended: permeation time >30 min. (level 2), material e.g. butyl or neopren. Observe glove manufacturers instructions.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Appearance	
Form	Powder
Colour	Blue

(b) (4)

[redacted]

Odour	None	

Important health safety and environmental information

pH	5 - 5.5	20 g/l
Boiling point	Not applicable	
Flash point	Not applicable	
Oxidising properties	None	
Solubility in water	80 g/l	at 30 °C
	80 g/l	90 °C

Other information

Melting point	> 250 °C	
Bulk density	657 kg/m3	
Thermal decomposition	230 °C	
Ignition temperature	480 °C	BAM

10. STABILITY AND REACTIVITY

Conditions to avoid	None.
Materials to avoid	None
Hazardous decomposition products	None under normal storage conditions

11. TOXICOLOGICAL INFORMATION

Acute toxicity			
- LD50 oral	> 2000 mg/kg	Rat	
Primary irritation			
(Skin)	Non-irritant	Rabbit	
(Eye)	Non-irritant	Rabbit	
Skin sensitisation	Sensitizing	Guinea Pig	OECD 406
Adverse effects in man	See 16 in MSDS		
Additional information			

12. ECOLOGICAL INFORMATION

Ecotoxicity

Bacterial toxicity			
	IC50	> 300 mg/l	3 hour
Fish toxicity	LC0	100 mg/l	48 hour Golden orfe
	LC50	> 100 mg/l	
Summary		Not toxic or harmful to aquatic organisms	

Persistance and degradability

Bioelimination	10-25%, DOC Analysis.	OECD 302B
Summary	Poorly eliminated by adsorption on effluent treatment sludge	
Behaviour in treatment plants	No inhibition. No nitrification inhibition known	

Additional Ecology Data

Phosphorus content	0 %	
Organohalogen content	0 %	
Metal content	2.04 %	Copper as organo-metal complex

(b) (4)

[redacted]

Tested material	Standardised product
Additional information	

13. DISPOSAL CONSIDERATIONS

Product disposal	Incineration, landfill. Observe local regulations.
Contaminated packaging	Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

KEEP AWAY FROM FOODSTUFFS

Not classified as dangerous goods

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Symbol and classification	Xi : Irritant
R-Phrases	R43 : May cause sensitisation by skin contact
S-Phrases	S22 : Do not breathe dust
	S24 : Avoid contact with skin
	S37 : Wear suitable gloves
Contains	C.I. Reactive Blue 21
EU Guideline	99/45

16. OTHER INFORMATION

Cases of respiratory sensitisation have been observed with reactive dyes.

Care should be taken to avoid inhalation.

Should an individual become sensitized a physician should be consulted and all contact with reactive dyes must cease immediately.

List of relevant R-phrases (Section 2)

R43 : May cause sensitisation by skin contact

Recommended restrictions on use

Huntsman textile, paper and leather dyes and chemicals are technical grade and unless otherwise stated or agreed are recommended only for industrial use in applications involving the pretreatment dyeing or finishing of textiles, paper or leather. Other intended uses including their use in consumer products governed by specific legislation or standards should be referred to the manufacturer. The data contained in the SDS apply only to Huntsman products sold under the stated trade names. Technical information in support will be provided by Huntsman at the request of competent authorities.

member of ETAD

MSDS Changes	15. REGULATORY INFORMATION
	S-Phrases

(b) (4)

[redacted]

(b)(4) Deficiencies and Responses to Deficiencies

(b)(4) Deficiencies and Responses to Deficiencies

(b)(4) Deficiencies and Responses to Deficiencies

(b)(4) Deficiencies and Responses to Deficiencies

(b)(4) Deficiencies and Responses to Deficiencies

(b) (4) [redacted]

Flammability: 2

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves.
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent.
Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/10/2005 08:47 PM

Last Updated: 11/06/2008 12:00 PM

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall ScienceLab.com be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if ScienceLab.com has been advised of the possibility of such damages.

(b)(4) Deficiencies and Responses to Deficiencies

(b)(4) Deficiencies and Responses to Deficiencies

(b)(4) Deficiencies and Responses to Deficiencies

(b) (4)

corresponding RQs	
SARA Section 302 Extremely Hazardous Substances	None of the chemicals in this product have a TPQ.
Section 313	No chemicals are reportable under Section 313.
Clean Air Act:	This material does not contain any hazardous air pollutants. This material does not contain any Class 1 Ozone depletors. This material does not contain any Class 2 Ozone depletors.
Clean Water Act:	None of the chemicals in this product are listed as Hazardous Substances under the CWA. None of the chemicals in this product are listed as Priority Pollutants under the CWA. None of the chemicals in this product are listed as Toxic Pollutants under the CWA.

(b) (4)

European Labeling in Accordance with EC Directives

Hazard Symbols:Not available

Risk Phrases:

Safety Phrases:

S 24/25 Avoid contact with skin and eyes.

(b) (4)

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantibility or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential, or exemplary damages howsoever arising, even if the company has been advised of the possibility of such damages.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Filligent

K101128/S001

May 25, 2010

Document Mail Center – WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAY 26 2010
Received

Attention: Dr Sheila Murphey and Mr Steven Elliott

Dear Dr. Murphey, Mr Elliott

Re: Supplement to 510(k) Premarket Notification – K101128

Our firm submitted a 510(k) premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128) on Thursday April 22, 2010. On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Medical Officer, Infection Control Devices Branch, was received requesting Filligent to provide further information (the ***FDA Request***). Our supplementary response has been in two stages. The first stage was submitted on Tuesday, May 4, 2010 and addressed questions 4 to 10 of the FDA Request (a copy of which is attached for easy reference). We hereby enclose the second stage to our supplementary response, which addresses the remaining queries of the FDA Request, namely questions 1 to 3 inclusive.

Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely

K16

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

To unsubscribe from this list, send an email to: CDRH_FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

May 25, 2010

Document Mail Center – WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Attention: Dr Sheila Murphey and Mr Steven Elliott

Dear Dr. Murphey, Mr Elliott

Re: Supplement to 510(k) Premarket Notification – K101128

Our firm submitted a 510(k) premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128) on Thursday April 22, 2010. On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Medical Officer, Infection Control Devices Branch, was received requesting Filligent to provide further information (the ***FDA Request***). Our supplementary response has been in two stages. The first stage was submitted on Tuesday, May 4, 2010 and addressed questions 4 to 10 of the FDA Request (a copy of which is attached for easy reference). We hereby enclose the second stage to our supplementary response, which addresses the remaining queries of the FDA Request, namely questions 1 to 3 inclusive.

Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Supplementary Response to FDA Request

Our firm has submitted a premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128, the "510(k) Submission"). On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Infection Control Devices Branch, was received requesting Filligent to provide further information:

As we review your 510(k) submission, it is very important that we have a complete description of the

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

10. Please state whether or not any "anti-fog" compound has been added to the polyurethane nose sponge on the Premium BF 200-3013 mask or where it is the presence of untreated polyurethane which is considered to provide the anti-fog function

If the above information is not already in the file, please provide it to Mr. Elliott and to me electronically as soon as you can. Please also send a copy of this material to the Document mail Center so that it can be officially added to the contents of your file.

We may have additional questions later as we proceed with this review. If that is the case, we will send them to you. We expect to request consultation from the Center for Drug Evaluation and Research (CDER) on this interesting submission. However, we must be sure before we place the request that all of the information which CDER will need will be available in the file. If you have any questions about the information needed, please let me know.

Thank you very much for your assistance in providing this information.

Regards,
Sheila A. Murphey, MD

* *

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

5. The MSDS sheets for citric acid, copper acetate, zinc acetate and CI Reactive Blue 21

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

6. Please provide the levels of citric acid, copper and zinc in your devices by ugm or mgm per unit of area such as cm^2 for your devices

See response to Question 7.

7. Please provide the total amounts of citric acid, copper and zinc per total, complete device for each of your mask models

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical face masks and are being

(b)(4) Deficiencies and Responses to Deficiencies

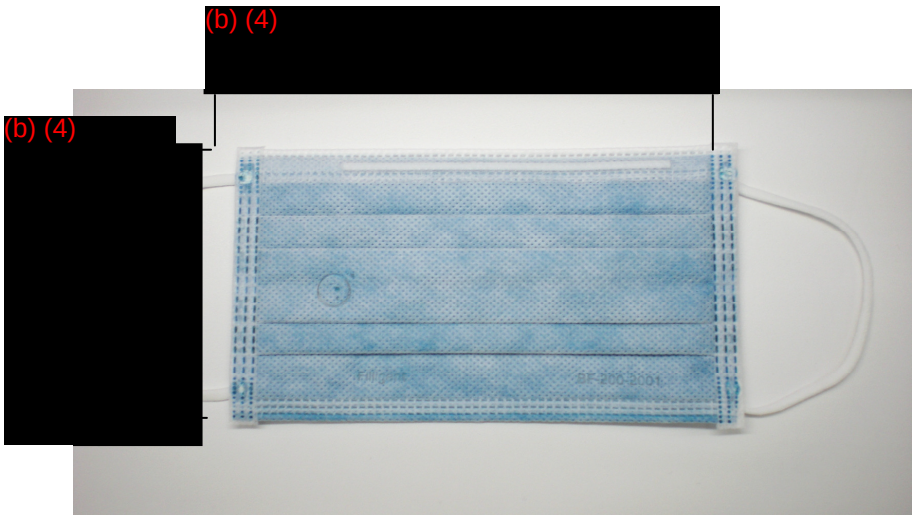
[redacted]

ear adjusters and an anti-fog nose insert. The major dimensions for each device are summarized in Table 2, and Figures 1 and 2. Both the Universal BF-200-2001 and Premium BF-200-3013 contain approximately the same total surface area of material (b) (4) [redacted] also refer to Table 15-5, page 15-4 of 510(k) submission).

Table 2 Major Dimensions of the BioFriend™ BioMask™ Surgical Facemasks

Major Dimensions	BioFriend™ BioMask™ Universal BF-200-2001	BioFriend™ BioMask™ Premium BF-200-3013
Length	(b) (4) [redacted]	
Width		
Total Surface Area		
Ear-loops		
Polyurethane Sponge		
Nose Strip		

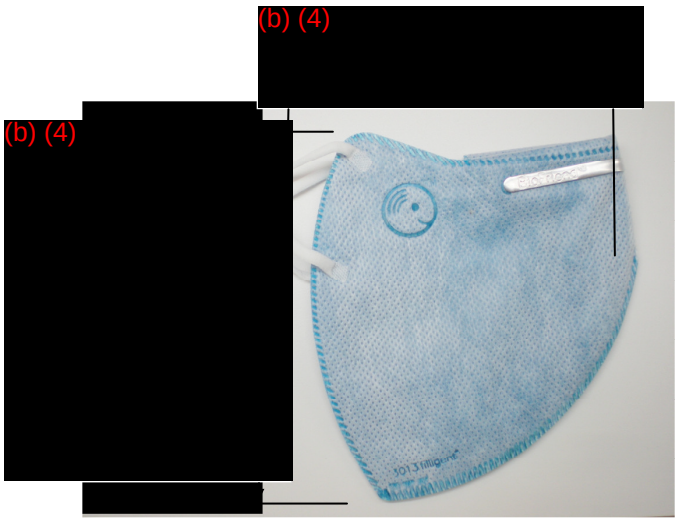
Figure 1 Major Dimensions of the BioFriend™ BioMask™ Universal BF-200-2001



Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Figure 2 Major Dimensions of the BioFriend™ BioMask™ Premium BF-200-3013



9. Please identify the contribution of the copper in CI Reactive Blue 21 to the antimicrobialactivity of your device

(b) (4)

[redacted]

10. Please state whether or not any "anti-fog" compound has been added to the polyurethane nose sponge on the Premium BF 200-3013 mask or where it is the presence of untreated polyurethane which is considered to provide the anti-fog function

No “anti-fog” compounds have been added to the polyurethane sponge. The presence of untreated polyurethane on the inside of the nose-flap is used to improve seal of the nose-flap around the nose to help prevent glasses and face shields from fogging.

[1] Lawton, E. A. (1958) The thermal stability of copper phthalocyanine. *J. Phys. Chem.*62 (3): 384

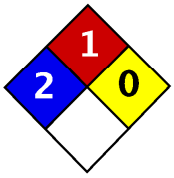
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b) (4)

[redacted]

Appendix 1-A: Citric Acid MSDS



Health	2
Fire	1
Reactivity	0
Personal Protection	E

Material Safety Data Sheet
Citric acid MSDS

Section 1: Chemical Product and Company Identification

Product Name: Citric acid

Catalog Codes: SLC5449, SLC2665, SLC4453, SLC1660, SLC3451

CAS#: 77-92-9

RTECS: GE7350000

TSCA: TSCA 8(b) inventory: Citric acid

CI#: Not available.

Synonym: 2-Hydroxy-1,2,3-propanetricarboxylic acid

Chemical Name: Citric Acid

Chemical Formula: C6H8O7

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Citric acid	77-92-9	100

Toxicological Data on Ingredients: Citric acid: ORAL (LD50): Acute: 5040 mg/kg [Mouse]. 3000 mg/kg [Rat].

Section 3: Hazards Identification

Potential Acute Health Effects:
Hazardous in case of eye contact (irritant), of inhalation (lung irritant). Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion. The amount of tissue damage depends on length of contact. Eye contact can result in corneal damage or blindness. Skin contact can produce inflammation and blistering. Severe over-exposure can produce lung damage, choking, unconsciousness or death.

Potential Chronic Health Effects:
Slightly hazardous in case of skin contact (sensitizer).
CARCINOGENIC EFFECTS: Not available.
MUTAGENIC EFFECTS: Not available.
TERATOGENIC EFFECTS: Not available.
DEVELOPMENTAL TOXICITY: Not available.
The substance may be toxic to teeth.
Repeated or prolonged exposure to the substance can produce target organs damage. Repeated exposure of the

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Appendix 1-A: Citric Acid MSDS

eyes to a low level of dust can produce eye irritation. Repeated skin exposure can produce local skin destruction, or dermatitis. Repeated inhalation of dust can produce varying degree of respiratory irritation or lung damage.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Skin Contact:
In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact:
Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: 1010°C (1850°F)

Flash Points: Not available.

Flammable Limits: LOWER: 0.28 Kg/M3 (Dust) UPPER: 2.29 Kg/M3 (Dust)

Products of Combustion: These products are carbon oxides (CO, CO2).

Fire Hazards in Presence of Various Substances:
Slightly flammable to flammable in presence of heat.
Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Slightly explosive in presence of open flames and sparks.
Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

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Appendix 1-A: Citric Acid MSDS

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Eliminate all ignition sources. Call for assistance on disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, reducing agents, metals, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:
Safety glasses. Lab coat. Gloves (impervious). Dust respirator. Be sure to use an approved/certified respirator or equivalent. The dust respirator should be used for conditions where exposure has exceeded recommended exposure limits, dust is apparent, and engineering controls(adequate ventilation) are not feasible.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:
No exposure guidelines have been established.
ACGIH, NIOSH and OSHA have not developed exposure limits for this product.
The exposure limits given below are for particulates not otherwise classified:
ACGIH: 10 mg/m3 TWA (Total Inhalable fraction); 3 mg/m3 TWA (Respirable fraction)
OSHA: 15 mg/m3 TWA (Total dust); 5 mg/m3 TWA (Respirable Fraction)

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Crystalline powde)

Odor: Odorless.

Taste: Acid. (Strong.)

Molecular Weight: 192.13 g/mole

Color: Not available.

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Appendix 1-A: Citric Acid

pH (1% soln/water): Not available.

Boiling Point: Decomposes.

Melting Point: 153°C (307.4°F)

Critical Temperature: Not available.

Specific Gravity: 1.665 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: The product is more soluble in water; log(oil/water) = -1.7

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water, diethyl ether.

Solubility:
Soluble in cold water, hot water, diethyl ether.
Insoluble in benzene.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents, reducing agents, metals, alkalis.

Corrosivity:
Corrosive in presence of aluminum, of zinc, of copper.
Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Incompatible with oxidizing agents, potassium tartrate, alkali, alkaline earth carbonates and bicarbonates, acetates, and sulfides, metal nitrates

Special Remarks on Corrosivity: Will corrode copper, zinc, aluminum and their alloys.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 3000 mg/kg [Rat].

Chronic Effects on Humans: May cause damage to the following organs: teeth.

Other Toxic Effects on Humans:

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Appendix 1-A: Citric Acid

Hazardous in case of inhalation (lung irritant).
Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion.

Special Remarks on Toxicity to Animals: LDL[Rabbit] - Route: oral; Dose: 7000mg/kg

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects:
Skin: Causes mild to moderate skin irritation. May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material.
Eyes: Causes moderate to severe eye irritation and possible injury.
Ingestion: May cause gastrointestinal (digestive) tract irritation with nausea, vomiting, diarrhea. Excessive intake may cause erosion of teeth and hypocalcemia (calcium deficiency in blood). May affect behavior/central nervous system (tremor, convulsions, muscle contraction or spasticity).
Inhalation: Causes moderate respiratory tract and mucous membrane irritation.
Chronic Potential Health Effects:
Frequent intake of citrated beverages may cause erosion of dental enamel and irritation of mucous membranes.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Citric acid

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): CLASS E: Corrosive solid.

DSCL (EEC):

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Appendix 1-A: Citric Acid

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R36/37/38- Irritating to eyes, respiratory system and skin.
S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S37/39- Wear suitable gloves and eye/face protection.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: e

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves (impervious).
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.
Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

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Potential Health Effects

Inhalation:
Causes irritation to respiratory tract, symptoms may include coughing, sore throat, and shortness of breath. May result in ulceration and perforation of respiratory tract. When heated, this compound may give off copper fume, which can cause symptoms similar to the common cold, including chills and stuffiness of the head.
Ingestion:
May cause burning pain in the mouth, esophagus, and stomach. Hemorrhagic gastritis, nausea, vomiting, abdominal pain, metallic taste, and diarrhea may occur. If vomiting does not occur immediately systemic copper poisoning may occur. Symptoms may include capillary damage, headache, cold sweat, weak pulse, kidney and liver damage, central nervous excitation followed by depression, jaundice, convulsions, blood effects, paralysis and coma. Death may occur from shock or renal failure.
Skin Contact:
May cause irritation with redness and pain.
Eye Contact:
Corrosive. May cause irritation, redness, pain, blurred vision, discoloration, and damage.
Chronic Exposure:
Prolonged or repeated skin exposure may cause dermatitis. Prolonged or repeated exposure to dusts of copper salts may cause discoloration of the skin or hair, blood and liver damage, ulceration and perforation of the nasal septum, runny nose, metallic taste, and atrophic changes and irritation of the mucous membranes.
Aggravation of Pre-existing Conditions:
Persons with pre-existing skin disorders, impaired liver, kidney, or pulmonary function, glucose 6-phosphate-dehydrogenase deficiency, or pre-existing Wilson's disease may be more susceptible to the effects of this material.

4. First Aid Measures

Inhalation:
Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
Ingestion:
Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. Call a physician.
Skin Contact:
In case of contact, wipe off excess material from skin then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Call a physician.
Eye Contact:
Immediately flush eyes with gentle but large stream of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Call a physician immediately.

5. Fire Fighting Measures

Fire:
Not considered to be a fire hazard. May form combustible fumes upon decomposition which may increase the flammability of a fire.
Explosion:
Reactions with incompatibles may pose an explosion hazard.
Fire Extinguishing Media:
Use any means suitable for extinguishing surrounding fire. Water spray may be used to keep fire exposed containers cool.
Special Information:
In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with

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full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

US Regulations (CERCLA) require reporting spills and releases to soil, water and air in excess of reportable quantities. The toll free number for the US Coast Guard National Response Center is (800) 424-8802. Ventilate area of leak or spill. Keep unnecessary and unprotected people away from area of spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Isolate from incompatible substances. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:
-OSHA Permissible Exposure Limit (PEL):
1 mg/m3 (TWA) for copper dusts & mists as Cu
-ACGIH Threshold Limit Value (TLV):
1 mg/m3 (TWA) for copper dusts & mists as Cu
Ventilation System:
A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.
Personal Respirators (NIOSH Approved):
If the exposure limit is exceeded and engineering controls are not feasible, a half facepiece particulate respirator (NIOSH type N95 or better filters) may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest.. A full-face piece particulate respirator (NIOSH type N100 filters) may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency, or respirator supplier, whichever is lowest. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.
Skin Protection:
Wear protective gloves and clean body-covering clothing.
Eye Protection:
Use chemical safety goggles and/or full face shield where dusting or splashing of solutions is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:
Dark green powder.
Odor:
Slight acetic acid odor.
Solubility:

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7.2 g/100 cc cold water; 20 g/100 cc hot water.
Density:
1.88
pH:
No information found.
% Volatiles by volume @ 21C (70F):
0
Boiling Point:
240C (464F) Decomposes.
Melting Point:
115C (239F)
Vapor Density (Air=1):
No information found.
Vapor Pressure (mm Hg):
No information found.
Evaporation Rate (BuAc=1):
No information found.

10. Stability and Reactivity

Stability:
Stable under ordinary conditions of use and storage.
Hazardous Decomposition Products:
May produce oxides of carbon and the contained metal.
Hazardous Polymerization:
Will not occur.
Incompatibilities:
Sodium hypobromite, acetylene, hydrazine, and nitromethane.
Conditions to Avoid:
Incompatibles.

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12. Ecological Information

Environmental Fate:
This material is expected to significantly bioaccumulate. This material has an experimentally-determined bioconcentration factor (BCF) of greater than 100. Bioaccumulation data for copper.
Environmental Toxicity:
This material is expected to be very toxic to aquatic life. The LC50/96-hour values for fish are less than 1 mg/l. The IC50/72-hour values for algae are less than 1 mg/l. Toxicity data for copper.

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[redacted]

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

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[redacted]

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16. Other Information

NFPA Ratings: Health: **2** Flammability: **0** Reactivity: **0**
Label Hazard Warning:
DANGER! CAUSES EYE BURNS. HARMFUL IF SWALLOWED. CAUSES IRRITATION TO SKIN AND RESPIRATORY TRACT.
Label Precautions:
Do not get in eyes.
Avoid breathing dust.
Keep container closed.
Use with adequate ventilation.
Wash thoroughly after handling.
Avoid contact with skin and clothing.
Label First Aid:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. In case of skin contact, wipe any excess material off skin and then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. In all cases, get medical attention.
Product Use:
Laboratory Reagent.
Revision Information:
No Changes.
Disclaimer:
****
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****

Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Deficiencies and Responses to Deficiencies

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(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

(b)(4) Deficiencies and Responses to Deficiencies

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Ingestion	Wash out mouth with water. Drink plenty of water.
Advice for the doctor	Symptomatic treatment
Further information	See section 16 of MSDS

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents	Waterspray, foam, powder, carbon dioxide.
Restrictions	No restrictions.
Fire/explosion hazard	None
Main combustion gas	Carbon, nitrogen and sulfur oxides
Personal protection	Self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal protection	Gloves, respiratory protection.
Environmental precautions	No special precautions
Spillage procedure	Damp down. Avoid dust. Scoop into marked containers for disposal as chemical waste. Flush residues away with water.

7. HANDLING AND STORAGE

Handling

Occupational hygiene	Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Storage

Fire precautions	No special measures required
Storage facilities	Store in a cool, dry area with adequate ventilation
Segregation	Keep away from alkali.
Storage conditions	Keep containers closed. Sensitive to heat over 40 °C.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits	None. Ensure adequate ventilation

Exposure Controls

Occupational exposure controls	
General Personal Protection	Gloves, respiratory protection.
Hand protection	Chemical resistant protective gloves (EN 374). Recommended: permeation time >30 min. (level 2), material e.g. butyl or neopren. Observe glove manufacturers instructions.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Appearance	
Form	Powder
Colour	Blue

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[redacted]

Odour	None		
Important health safety and environmental information			
pH	5 - 5.5		20 g/l
Boiling point	Not applicable		
Flash point	Not applicable		
Oxidising properties	None		
Solubility in water	80 g/l		at 30 °C
	80 g/l		90 °C
Other information			
Melting point	> 250 °C		
Bulk density	657 kg/m3		
Thermal decomposition	230 °C		
Ignition temperature	480 °C	BAM	

10. STABILITY AND REACTIVITY

Conditions to avoid	None.
Materials to avoid	None
Hazardous decomposition products	None under normal storage conditions

11. TOXICOLOGICAL INFORMATION

Acute toxicity			
- LD50 oral	> 2000 mg/kg	Rat	
Primary irritation			
(Skin)	Non-irritant	Rabbit	
(Eye)	Non-irritant	Rabbit	
Skin sensitisation	Sensitizing	Guinea Pig	OECD 406
Adverse effects in man	See 16 in MSDS		
Additional information			

12. ECOLOGICAL INFORMATION

Ecotoxicity

Bacterial toxicity			
	IC50	> 300 mg/l	3 hour
Fish toxicity	LC0	100 mg/l	48 hour Golden orfe
	LC50	> 100 mg/l	
Summary		Not toxic or harmful to aquatic organisms	

Persistance and degradability

Bioelimination	10-25%, DOC Analysis.	OECD 302B
Summary	Poorly eliminated by adsorption on effluent treatment sludge	
Behaviour in treatment plants	No inhibition. No nitrification inhibition known	

Additional Ecology Data

Phosphorus content	0 %	
Organohalogen content	0 %	
Metal content	2.04 %	Copper as organo-metal complex

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[redacted]

Tested material	Standardised product
Additional information	

13. DISPOSAL CONSIDERATIONS

Product disposal	Incineration, landfill. Observe local regulations.
Contaminated packaging	Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

KEEP AWAY FROM FOODSTUFFS

Not classified as dangerous goods

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Symbol and classification	Xi : Irritant
R-Phrases	R43 : May cause sensitisation by skin contact
S-Phrases	S22 : Do not breathe dust
	S24 : Avoid contact with skin
	S37 : Wear suitable gloves
Contains	C.I. Reactive Blue 21
EU Guideline	99/45

16. OTHER INFORMATION

Cases of respiratory sensitisation have been observed with reactive dyes.

Care should be taken to avoid inhalation.

Should an individual become sensitized a physician should be consulted and all contact with reactive dyes must cease immediately.

List of relevant R-phrases (Section 2)

R43 : May cause sensitisation by skin contact

Recommended restrictions on use

Huntsman textile, paper and leather dyes and chemicals are technical grade and unless otherwise stated or agreed are recommended only for industrial use in applications involving the pretreatment dyeing or finishing of textiles, paper or leather. Other intended uses including their use in consumer products governed by specific legislation or standards should be referred to the manufacturer. The data contained in the SDS apply only to Huntsman products sold under the stated trade names. Technical information in support will be provided by Huntsman at the request of competent authorities.

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MSDS Changes	15. REGULATORY INFORMATION
	S-Phrases

(b)(4) Deficiencies and Responses to Deficiencies

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Flammability: 2

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves.
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent.
Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/10/2005 08:47 PM

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corresponding RQs	
SARA Section 302 Extremely Hazardous Substances	None of the chemicals in this product have a TPQ.
Section 313	No chemicals are reportable under Section 313.
Clean Air Act:	This material does not contain any hazardous air pollutants. This material does not contain any Class 1 Ozone depletors. This material does not contain any Class 2 Ozone depletors.
Clean Water Act:	None of the chemicals in this product are listed as Hazardous Substances under the CWA. None of the chemicals in this product are listed as Priority Pollutants under the CWA. None of the chemicals in this product are listed as Toxic Pollutants under the CWA.

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European Labeling in Accordance with EC Directives

Hazard Symbols:Not available

Risk Phrases:

Safety Phrases:

S 24/25 Avoid contact with skin and eyes.

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Supplementary Response to FDA Request
Stage II – May 25, 2010.

(b)(4) Deficiencies and Responses to Deficiencies

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K101128/S2

FDA CDRH DMC

FEB 22 2011

Received

K40

February 19, 2011

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information - 510(k) Premarket Notification – K101128

This letter constitutes Filligent (HK) Limited's response to CDRH's request for additional information, which was dated December 29, 2010. It forms part of our total submissions to date – namely:

- 510(k) Premarket Notification, dated April 20, 2010
- Additional Information, dated June 4, 2010 - submitted in response to CDRH's request for additional information, which was dated and received by email on Wednesday, April 28, 2010
- Additional Information, dated November 13, 2010 - submitted in response to CDRH's request for additional information, which was dated May 21, 2010

Each question, subject of this request for addition information, is listed in the following pages, together with our response.

We believe that this response will provide adequate information to reach a determination of substantial equivalence. Nevertheless, if you require additional information, please do not hesitate to contact us at:

Filligent (HK) Limited

7th Floor, 69 Jervois Street

Sheung Wan, Hong Kong

Telephone: +852 2542 2400

Facsimile: +852 2542 2411

Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

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February 19, 2011

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Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

1 510(k) Summary

CDRH Questions

1. In the Indications for Use/Statement of Intended Use added to the 510(k) Summary, the phrase "Which form… in biologicals" is incorrect. Performance testing on this device has examined only influenza viruses. Please replace "biological" with "influenza viruses."

2. In the Indications for Use/Statement of Intended Use added to the 510(k) Summary, the phrase "…tests against seasonal, pandemic, avian, swine, and equine Influenza viruses including…" is misleading because it implies that additional strains of virus have been tested. Please revise this statement to "..tests against these specific Influenza strains – Influenza A H1N1 (A/California/07/2009 (2009 pandemic strain)), A Brisbane/59/2007…."

3. Please provide the exact scientific strain identification for "Avian Influenza H9N2".

4. Please remove the sentence, "These devices also help to protect the wearer from splash and spray of blood and body fluids" as previously requested. This wording is not included in 21 CFR 878.4040.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

1. In the Indications for Use/Statement of Intended Use added to the 510(k) Summary, the phrase "Which form… in biologicals" is incorrect. Performance testing on this device has examined only influenza viruses. Please replace "biological" with "influenza viruses."

The wording "biologicals" has been removed and replaced with "influenza viruses" in the Indications for Use/Statement of Intended Use.

In addition within this phrase the wording "electrostatic" has been interchanged with the synonym "ionic" to more specifically describe the nature of the bond.

The phrase now reads "which form ionic bonds with negatively-charged side groups on influenza virus."

The amended 510(k) summary is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

2. In the Indications for Use/Statement of Intended Use added to the 510(k) Summary, the phrase "…tests against seasonal, pandemic, avian, swine, and equine Influenza viruses including…" is misleading because it implies that additional strains of virus have been tested. Please revise this statement to "..tests against these specific Influenza strains – Influenza A H1N1 (A/California/07/2009 (2009 pandemic strain)), A Brisbane/59/2007…."

The wording "… tests against seasonal, pandemic, avian, swine and equine Influenza viruses including…" has been removed from the Indications for Use/Statement of Intended Use, and replaced with:

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions."

In addition, the influenza viruses: B/Brisbane/60/2008, Influenza A/Hong Kong/8/68 and Influenza A/Victoria/3/75 have been removed from the Indications for Use /Statement of Intended Use as virucidal performance against these viruses have not yet met the requirements of the FDA.

The amended 510(k) summary is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

3. Please provide the exact scientific strain identification for "Avian Influenza H9N2".

The exact scientific strain identification for Avian Influenza H9N2 is Influenza A/Turkey/Wisconsin/1966.

The amended 510(k) summary is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

4. Please remove the sentence, "These devices also help to protect the wearer from splash and spray of blood and body fluids" as previously requested. This wording is not included in 21 CFR 878.4040.

The sentence "These devices also help to protect the wearer from splash and spray of blood and body fluids" has been removed.

The amended 510(k) summary is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5 510(k) Summary

5.1 Applicant and Correspondent

Name: Filligent (HK) Limited

Address: 7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

Contact Person: Melissa Mowbray-d'Arbela
Chief Executive Officer

Phone: (852) 2542 2400

Date of Preparation: February 19, 2011

5.2 Manufacturer

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

5.3 Name of Device

Trade/Proprietary/Model Name: BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A
Premium BF-200-3013A

Common Name: Surgical Facemask

Classification Name: Mask, Surgical

Classification Regulation: 878.4040

Panel: General Hospital

Product Code: FXX

Recognized Performance Std: ASTM F2100-07 (refer to submission)

5.4 Devices to Which New Device is Substantially Equivalent

Device Name: Prestige Ameritech Face Mask
Manufacturer: Prestige Ameritech
Reference: K061716

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.5 Device Description

The BioFriend™ BioMask™ surgical facemask is offered in two mask styles, Model: BF-200-2001A ("Universal") and Model: BF-200-3013A ("Premium"). The Universal model is a standard flat mask with pleats, while the Premium model is flat-folded and expands into a convex-shaped mask. The Premium model also has ear adjusters and an anti-fog nose flap. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in these devices are typical construction materials commonly used in surgical facemasks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second inner layer is treated with copper and zinc. Both layers inactivate influenza viruses using different mechanisms of action. Masks are held in place on the wearer with elastic loops and contain a malleable metal nosepiece strip.

5.6 Statement of Intended Use

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions.

There are two models: (1) Universal (BF-200-2001A) - is a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.7 Summary of Technological Characteristics

The BioFriend™ BioMask™ surgical facemasks have substantially equivalent filter and barrier properties as the predicate device, and conform to the recognized FDA consensus standard ASTM F2100-07 Standard Specification for Performance of Materials used in Medical Face Masks. Both models of the BioFriend™ BioMask™ surgical facemask are constructed from the same materials and layers, and are identical in all respects other than shape. The outer layer of both models is coated with a hydrophilic plastic that allows aerosolized droplets contacting the surface of the mask to be rapidly absorbed into the inner layers. Both the outer and second inner layers are treated with different compounds that independently inactivate viruses through different mechanisms of action. Laboratory *(in vitro)* test results demonstrate that the BioFriend™ BioMask™ surgical facemasks kill ("inactivate") 99.99% (≥4-logs) of 15 different strains of Influenza A and B viruses, including the circulating 2009 pandemic H1N1, recent vaccine isolates, major reassortments and avian, swine and equine isolates after 5 minutes contact with the mask surface.

The BioFriend™ BioMask™ surgical facemasks have been tested for, and appropriately passed standardized tests for, fluid penetration resistance, particulate filtration efficiency, bacterial filtration efficiency, flammability, and breathing resistance. The device as a whole has been shown to be biocompatible through standardized tests for irritation, sensitization and extractables.

The materials of construction used in the BioFriend™ BioMask™ surgical facemasks are equivalent to those of the predicate device. The devices as a whole are substantially equivalent to the predicate device.

5.8 Brief description of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

- Bacterial Filtration Efficiency – ASTM F2101
- Sub-micron Particulate Filtration Efficiency – ASTM F2299
- Fluid Penetration Resistance – ASTM F1862
- Breathing Resistance – MIL-M-3654C
- Flammability Testing – 16 CFR 1610
- Biocompatibility, Irritation – ISO 10993-10
- Biocompatibility, Sensitization – ISO 10993-10
- Biocompatibility, Chemical Characterization – ISO 10993-18

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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5.9 Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Not applicable.

5.10 Conclusions drawn from the nonclinical and clinical tests

Standardized testing has shown that the construction materials used in both models of the BioFriend™ BioMask™ surgical facemask are substantially equivalent to those of the predicate device. The devices as a whole have been demonstrated to be biocompatible through irritation and sensitization testing, with toxicological assessment of the devices' components which could potentially be released with inhalation or salivary contact, indicating the devices are safe for use in the intended application. Laboratory testing has demonstrated the devices' efficacy. Both models of the BioFriend™ BioMask™ surgical facemask have been shown to be substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

For the purpose of clarity we wish to discuss the role of citric acid. It has been shown that citric acid may be transferred from the outer active layer of polypropylene coated with hydrophilic plastic to the inner active layer of cellulose/polyester with copper and zinc as a result of liquid absorption from the outer active layer, however neither the transfer of, nor the presence of citric acid required for influenza inactivation in the inner active layer. Citric acid is not required in order for the inner active layer to inactivate influenza virus, nor does it interfere with virus inactivation in the inner active layer. Each of the outer and inner active layers are independently capable of inactivating influenza virus using different mechanisms of action which when combined in the final device have been demonstrated to reduce influenza virus load by ≥4-log on 5 minutes contact. Critical aspects of the BioFriend™ BioMask™ surgical facemask and how each active layer functions independently to inactivate influenza virus are discussed below:

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Neither the outer active nor inner active layers in any way rely upon the compounds present in the other layer to respectively inactivate influenza virus. Although it has been shown that citric acid may be transferred from the outer active layer of polypropylene coated with hydrophilic plastic to the inner active layer of cellulose/polyester with copper and zinc as a result of liquid absorption from the outer active layer, neither the transfer of, nor the presence of citric acid is required for influenza inactivation in the inner active layer. Moreover, as shown by previously published studies, the presence of acid in combination with metal ions is not detrimental to this inner active layer, and is beneficial by further enhancing anti-viral efficacy (Rennie *et al.*, 2007- appended to Section 11 of the 510(k) Premarket Notification dated April 20, 2010).

As presented in Section 2, Question 6 of Additional Information dated November 13, 2010, two independent laboratory studies were carried out in order to demonstrate the absorptive capacity of the outer active layer and the absorption of liquid from the outer active layer to the inner active layer of the BioFriend™ BioMask™ surgical facemask.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

3 Indications for Use

CDRH Questions

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

7. Please amend your indication for use statement to include the following corrections:

- **The phrase "Which form…on biological" is incorrect. Performance testing on this device has examined only influenza viruses. Please replace "biological" with "influenza viruses."**

The phrase "Which form… on biological" has been removed and replaced with "influenza viruses."

In addition within this phrase the wording "electrostatic" has been interchanged with the synonym "ionic" to more specifically describe the nature of the bond. The phrase now reads "which form ionic bonds with negatively-charged side groups on influenza virus."

- **The phrase "…tests against seasonal, pandemic, avian, swine and equine Influenza viruses including…" is misleading because it implies that additional strains of virus have been tested. Please revise this statement to "…tests against these specific Influenza viruses – Influenza A H1N1 (A/California/07/2009 (2009 pandemic strain)), A Brisbane/59/2007..."**

The phrase "… tests against seasonal, pandemic, avian, swine and equine Influenza viruses including…" has been removed and replaced with

"The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007,A/Wisconsin/67/2005), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions."

In addition, the influenza viruses: B/Brisbane/60/2008, Influenza A/Hong Kong/8/68 and Influenza A/Victoria/3/75 have been removed from the Indications for Use /Statement of Intended Use as virucidal performance against these viruses have not yet met the requirements of the FDA.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

- **Please remove the sentence "These devices also help to protect the wearer from splash and spray of blood and body fluids" as previously requested. This wording is not included in 21 CFR 878.4040.**

The sentence "These devices also help to protect the wearer from splash and spray of blood and body fluids" has been removed.

- **Please provide the exact strain identification for "Avian Influenza H9N2."**

The exact scientific strain identification for Avian Influenza H9N2 is Influenza A/Turkey/Wisconsin/1966.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

4 Indications for Use Statement

510(k) Number:

K101128.

Device Name:

BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A

Indications for Use:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007,A/Wisconsin/67/2005,), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions."

Prescription Use _____	AND/OR	Over-The Counter Use ___X___
(21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded and expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of microorganisms, body fluids and particulate material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

4 Labeling

CDRH Questions

8. On the device labeling, you have used a much smaller font size to indicate that the mask kills 99.9% of tested flu viruses. This may be misleading. Please place the word "tested" in normal or larger print in the phrases below (as indicated in red) to clarify to users that only a few (18) strains of influenza have been tested against this mask.

"Kills 99.9% of tested Flu Viruses tested *"
"Inactivates 99.99% of tests H1N1 influenza viruses tested *"

9. In the revised device labeling the phrase "Seasonal and pandemic flu strains* including swine flu and bird flu*" appears to be too broad and deciphering the significance of the asterisks may difficult for the reader. This phrase should be revised since, as presently written, it does not clearly state that the BioMask™ has been tested only against certain influenza strains. Adding "testing" or "tested" at the beginning could be considered.

10. "Protective" without further explanation implies a claim for protection against the disease influenza. This should be revised to make it very clear that no clinical benefit from the use of this device has been demonstrated.

11. "Part of a range of innovative products" is not part of this submission which included only a single device. Please delete this phrase.

12. The label statement "How it works: The BioMask™ has a hydrophilic plastic coating that draws aerosol droplets away from the surface and into the inner layers where influenza viruses are inactivated" has not yet been supported. It is not yet clear how many viable influenza viruses reach the 2nd layer to be killed there. Please provide supporting data or remove this claim.

13. The phrase "† when used as intended," is vague and confusing as a free-standing phrase. Please explain this instruction in detail or delete it.

14. The phrase "This mask does not contain natural latex" should be revised to say "natural rubber latex" for accuracy.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

15. Please add a Caution to the device labeling which advises persons with hypersensitivity to copper or zinc to avoid the use of this device.

16. Please remove all symbols from the labeling of this device unless they are accompanied by English language explanation of the symbol.

17. The “Premium” BioMask™ should add the Caution that the small “ear adjuster” beads may pose a choking hazard to young children if separated from the device. This device should be kept away from children and discarded in a manner which keeps it away from them.

18. The labeling contains an “easy breathing” claim. This claim is vague and could be misinterpreted. Please remove the “easy breathing” claim from the device labeling.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

8. On the device labeling, you have used a much smaller font size to indicate that the mask kills 99.9% of tested flu viruses. This may be misleading. Please place the word "tested" in normal or larger print in the phrases below (as indicated in red) to clarify to users that only a few (18) strains of influenza have been tested against this mask.

"Kills 99.9% of tested Flu Viruses tested *"
"Inactivates 99.99% of tests H1N1 influenza viruses tested *"

The word "tested" has been placed in the following phrases and in larger print -
"Kills 99.9% of tested Flu Viruses tested *"
"Inactivates 99.99% of H1N1 influenza virus tested *"

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

9. In the revised device labeling the phrase "Seasonal and pandemic flu strains* including swine flu and bird flu*" appears to be too broad and deciphering the significance of the asterisks may difficult for the reader. This phrase should be revised since, as presently written, it does not clearly state that the BioMask™ has been tested only against certain influenza strains. Adding "testing" or "tested" at the beginning could be considered.

The labeling phrase, "seasonal and pandemic flu strains* including swine flu and bird flu*" has been revised to "tested seasonal and pandemic flu strains* including swine flu and bird flu*".

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

10. "Protective" without further explanation implies a claim for protection against the disease influenza. This should be revised to make it very clear that no clinical benefit from the use of this device has been demonstrated.

"Protective" has been removed from the packaging as requested and amended to "high barrier protection," in reference to the mask being a High Barrier Surgical Face Mask meeting ASTM F2100-07 Standards.

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

11. "Part of a range of innovative products" is not part of this submission which included only a single device. Please delete this phrase.

The phrase "Part of a range of innovative products" has been deleted from the device labeling as requested.

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Deficiencies and Responses to Deficiencies

(b)(4) Deficiencies and Responses to Deficiencies

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(b)(4) Deficiencies and Responses to Deficiencies

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

13. The phrase "† when used as intended," is vague and confusing as a free-standing phrase. Please explain this instruction in detail or delete it.

The phrase "† when used as intended," has been deleted from the labeling as requested.

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

14. The phrase "This mask does not contain natural latex" should be revised to say "natural rubber latex" for accuracy.

The phrase "This mask does not contain natural latex" has been revised to, "This mask does not contain natural rubber latex" as requested.

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

15. Please add a Caution to the device labeling which advises persons with hypersensitivity to copper or zinc to avoid the use of this device.

The cautionary statement, “Do not use if hypersensitive to copper or zinc” has been added to the labeling as requested.

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

16. Please remove all symbols from the labeling of this device unless they are accompanied by English language explanation of the symbol.

All symbols on the labeling of the device are now accompanied by English language explanations of the relevant symbols, or have been removed entirely.

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

17. The "Premium" BioMask™ should add the Caution that the small "ear adjuster" beads may pose a choking hazard to young children if separated from the device. This device should be kept away from children and discarded in a manner which keeps it away from them.

The cautionary statement, "Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately," has been added to the labeling of the Premium BioFriend™ BioMask™ surgical facemask.

The amended labeling is provided at the end of this section.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

(b)(4) Deficiencies and Responses to Deficiencies

(b)(4) Deficiencies and Responses to Deficiencies

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Revised Labeling

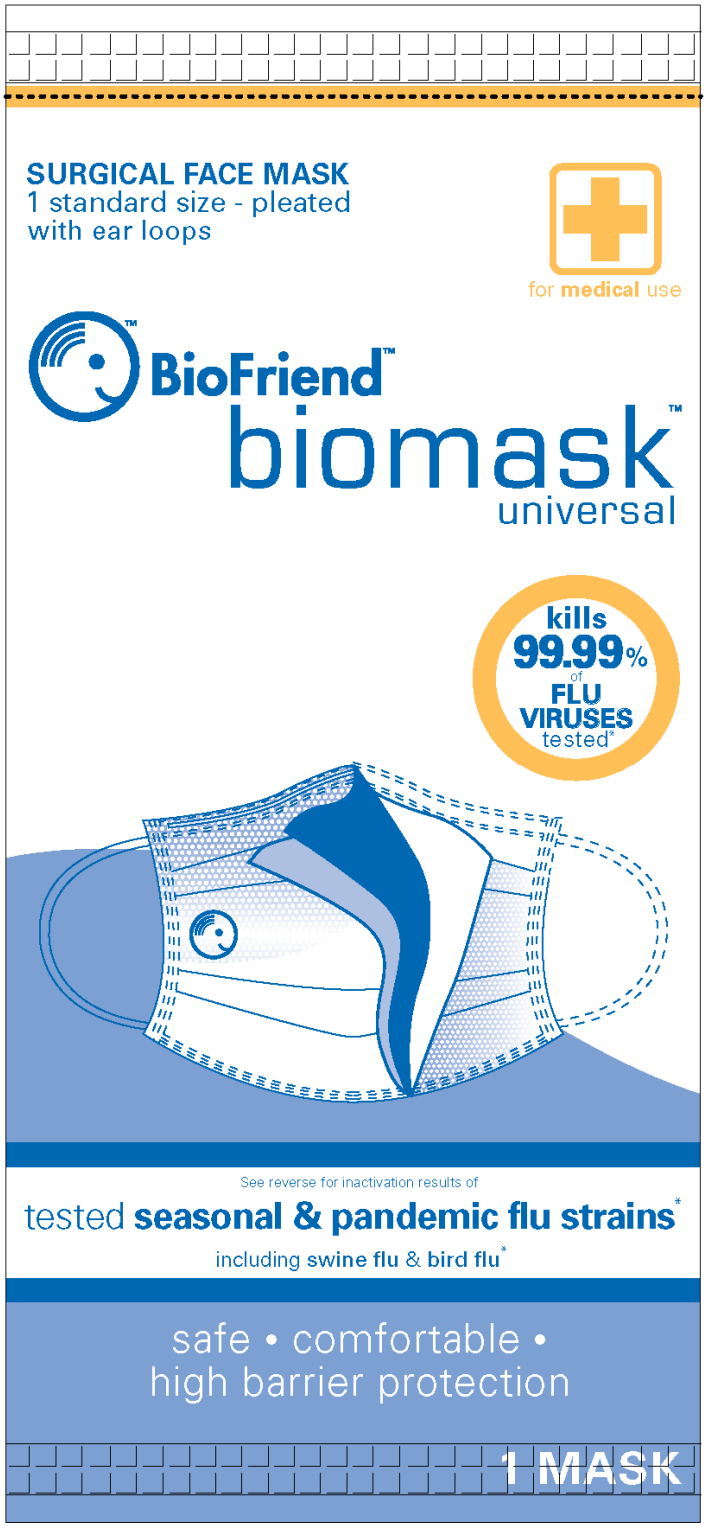
The revised labeling for the BioFriend™ BioMask™ surgical facemask is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Bag - Principal Display Panel - Front



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Bag – Reverse

BioFriend™ biomask™ universal

EXP: XX/XX/XXXX
LOT: XXXXXXX

High Barrier
Surgical Face Mask
Meets ASTM F2100-07 Standard

- Easy breathing
- Safe, smart & simple
- Comfortable face-design

inactivates **99.99%** of **H1N1** influenza virus tested*

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the outer surface of the mask. The first and second layers of the mask are treated with different compounds that inactivate influenza viruses.

INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively charged side groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) **99.99% of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/ 2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

Powered by BioFriend™ technology.

WARNINGS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- Do not use if hypersensitive to copper or zinc.
- Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately.
- This mask does not contain natural rubber latex.
- For use in medical settings only.
- For adult use only.

***Kills (inactivates) 99.99%** of the following tested **influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal
Human (H1N1), A/Brisbane/59/2007
Human (H1N1), A/Wisconsin/10/98
Human (H1N1), A/New Jersey/8/76
Human (H3N2), A/Brisbane/10/2007
Human (H3N2), A/Wisconsin/67/2005
Human, B/Florida/4/2006
Human, B/Lee/40
Pandemic
Pandemic H1N1, A/California/07/09
Human (H2N2), A/2/Japan/305/57
Avian
Avian (H5N1), NIBRG-14
Duck (H5N2), A/Duck/PA/10218/84
Avian (H9N2), Turkey/Wisconsin/66
Swine & Equine
Swine (H1N1), A/Swine/1976/31
Equine (H3N8), A/Equine/2/Miami/63
Other
Human (H1N1) A/PR/8/34

Store between –20°C & +35°C
Relative humidity <85%

Pragmatic • Scientific • Patented

Innovation by:
filligent
creating global health solutions
Website: usa.filligent.com
Email: contact.us@filligent.com
© Filligent Limited 2011. Made in China.
Patents pending. All rights reserved.
Manufactured by: Filligent (HK) Limited
7th floor, 69 Jervois Street,
Sheung Wan, Hong Kong
Re-order no.:
BF-200-2001A/P-1359/W-1359)

4 897026 663847

DISPOSABLE • SINGLE USE ONLY

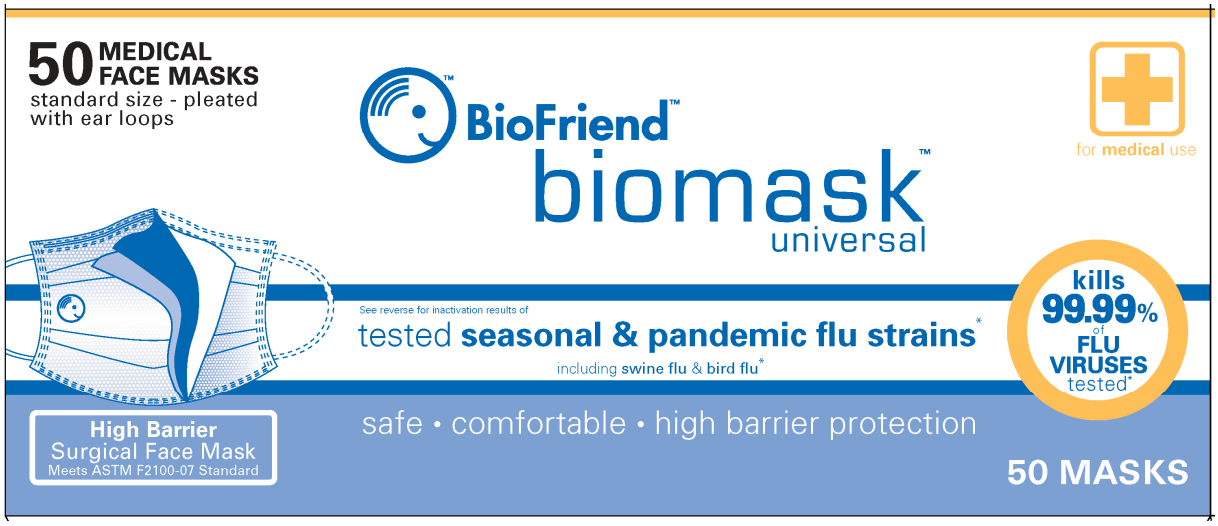
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Complete Box

Box - Principal Display Panel – Front & Reverse



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

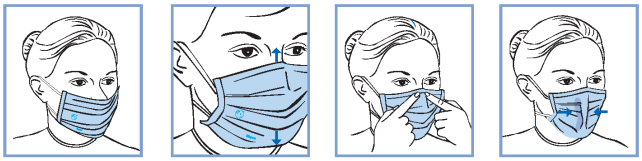
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box - Side Panel 1

BioFriend™
biomask™
universal

FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask.



1 Put loops around ears.
2 Adjust mask over nose & under chin.
3 Press forefingers down on both sides of nose.
4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

DISPOSABLE • SINGLE USE ONLY

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the surface of the mask and into the inner layers where influenza viruses are killed (inactivated).

* **Kills (inactivates) 99.99%** of the following tested **influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal	Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human (H3N2), A/Victoria/3/75 Human, B/Brisbane/60/2008 Human, B/Florida/4/2006 Human, B/Lee/40
Pandemic	Pandemic H1N1, A/California/07/09 Human (H3N2), A/Hong Kong/8/68 Human (H2N2), A/2/Japan/305/57
Avian	Avian (H5N1), NIBRG-14 Duck (H5N2), A/Duck/PA/10218/84 Avian (H9N2), Turkey/Wisconsin/66
Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

Powered by BioFriend™ technology.

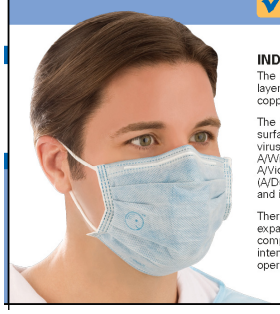
Box – Side Panel 2

BioFriend™
biomask™
universal

DISPOSABLE
SINGLE USE ONLY

- Easy breathing
- Safe, smart & simple
- Comfortable face-design

inactivates **99.99%** of **H1N1** influenza virus tested*



INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form electrostatic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) **99.99% of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, A/Hong Kong/8/68, A/Victoria/3/75), H2N2 (A/2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/ Miami/63); and influenza B strains: (B/Brisbane/60/2008, B/Florida/4/2006, B/Lee/40), under tested contact conditions.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

WARNINGS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- Do not use if hypersensitive to copper or zinc.
- Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately.
- This mask does not contain natural rubber latex.
- For use in medical settings only.
- For adult use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box – Lid

Box – Bottom

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-3013A

Bag - Principal Display Panel - Front

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-3013A

Bag - Reverse

BioFriend™
biomask™
premium

- Easy breathing
- Safe, smart & simple
- Comfortable face-design

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the outer surface of the mask. The first and second layers of the mask are treated with different compounds that inactivate influenza viruses.

INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) **99.99% of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, H2N2 (A/2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

Powered by BioFriend™ technology.

innovation by:
filligent™ enabling global health choices

Pragmatic • Scientific • Patented

Store between –20˚C & +35˚C
Relative humidity <85%

EXP: XX/XX/XXXX
LOT: XXXXXXX

High Barrier
Surgical Face Mask
Meets ASTM F2100-07 Standard

inactivates
99.99% of
H1N1
influenza virus
tested*

***Kills (inactivates) 99.99%** of the following tested **influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal	Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human, B/Florida/4/2006 Human, B/Lee/40
Pandemic	**Pandemic H1N1, A/California/07/09** Human (H2N2), A/2/Japan/305/57
Avian	Avian (H5N1), NIBRG-14 Duck (H5N2), A/Duck/PA/10218/84 Avian (H9N2), Turkey/Wisconsin/66
Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

WARNINGS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- Do not use if hypersensitive to copper or zinc.
- Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately.
- This mask does not contain natural rubber latex.
- For use in medical settings only.
- For adult use only.

DISPOSABLE • SINGLE USE ONLY

Website: usa.filligent.com
Email: contact.us@filligent.com

© Filligent Limited 2011. Made in China.
Patents pending. All rights reserved.

Manufactured by: Filligent (HK) Limited
7th floor, 69 Jervois Street,
Sheung Wan, Hong Kong

Re-order no.:
BF-200-3013A/P-1360(W-1360)

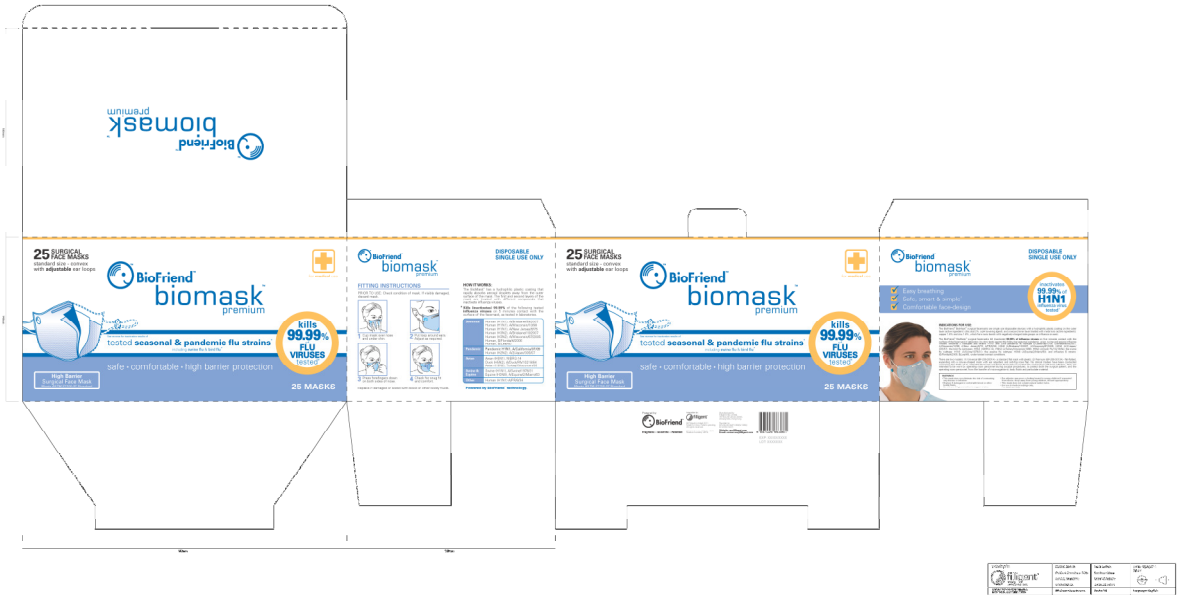
4 897026 663854

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-3013A

Complete Box



Box - Principal Display Panel – Front & Reverse

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Box - Side Panel 1

BioFriend™
biomask™
premium

DISPOSABLE SINGLE USE ONLY

FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask.

1 Cup mask over nose and under chin.

2 Put loop around ears. Adjust as required.

3 Press forefingers down on both sides of nose.

4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

HOW IT WORKS:

The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the outer surface of the mask. The first and second layers of the mask are treated with different compounds that inactivate influenza viruses.

* **Kills (inactivates) 99.99%** of the following tested **influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal	Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human, B/Florida/4/2006 Human, B/Lee/40
Pandemic	Pandemic H1N1, A/California/07/09 Human (H2N2), A/2/Japan/305/57
Avian	Avian (H5N1), NIBRG-14 Duck (H5N2), A/Duck/PA/10218/84 Avian (H9N2), Turkey/Wisconsin/66
Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

Powered by BioFriend™ technology.

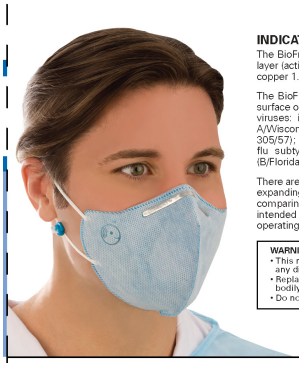
Box – Side Panel 2

BioFriend™
biomask™
premium

DISPOSABLE SINGLE USE ONLY

- Easy breathing
- Safe, smart & simple†
- Comfortable face-design

inactivates **99.99%** of **H1N1** influenza virus tested*



INDICATIONS FOR USE:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill (inactivate) **99.99% of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, H2N2 (A/2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/ PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

WARNINGS

- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- Do not use if hypersensitive to copper or zinc.
- Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately.
- This mask does not contain natural rubber latex.
- For use in medical settings only.
- For adult use only.

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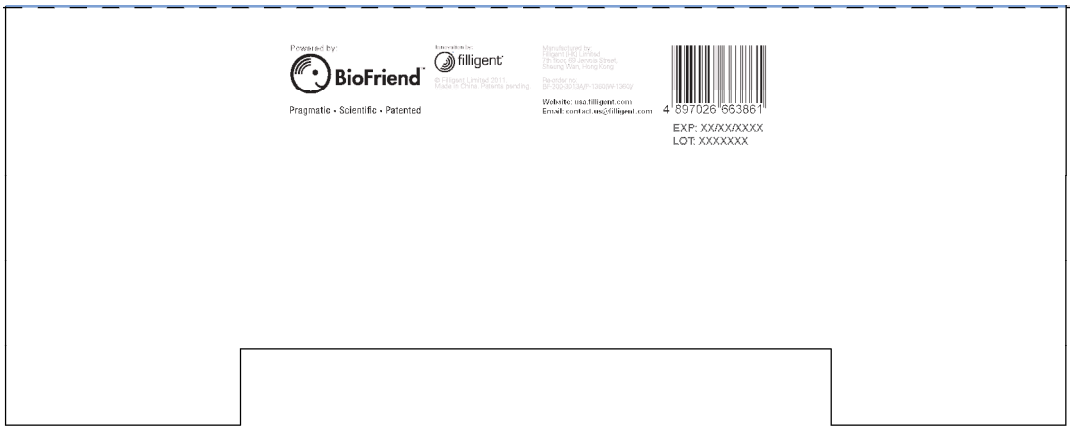
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box – Lid

Box – Bottom



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30. Please provide therapeutic indices for each influenza type/subtype.

The term “therapeutic” relates to the treatment of disease or disorders by remedial agents or methods. The BioFriend™ BioMask™ surgical facemask is a virucidal medical device, the purpose of which is not to treat disease, but to inactivate influenza virus on contact with the surface of facemask material.

Therapeutic indices cannot be determined for biological entities, including viruses. Only drugs and pharmacologicals having specific therapeutic indices based upon LD50 (Median Lethal Dose) and ED50 (Effective Dose for 50% of the Population) values. To the best of our knowledge there is no known method to deduce the number of infectious virions that would result in human infection as this relies on many factors such as immune status and genetic predisposition.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

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All $TCID_{50}$ testing specifically also includes a Cytotoxicity Control to determine whether any residual active ingredient that may be present following extraction impacts non-specifically upon the MDCK host-cell line which could inadvertently be interpreted as virus-specific cellular kill. The inclusion of all other necessary positive and negative controls accounts for any other non-specific virus loss that may occur within system, values of which are subtracted from the final log-inactivation value.

Furthermore, all $TCID_{50}$ testing includes controls which account for any virus loss, non-specific activity, and impact of all processes and solutions upon both the influenza virus and the MDCK cell line. within the experimental system include: 1) A Non-treated Control Mask sample, 2) a Virus Input (No Mask) Control sample, 3) a Medium-challenge Run (for Neutralizer Effectiveness and Viral Interference) control, 4) a Cytotoxicity Control, 5) Cell viability/media sterility control, 6) Virus Stock Titer control (an aliquot of virus is applied directly and in dilutions onto the host cells to confirm the titer of the stock virus used for testing). Any loss of virus or non-specific MDCK cellular-kill within this system should be consistent between control and test samples, and accounted for in the subsequent calculations.

Finally, at the conclusion of a test, the “Test Acceptance Criteria” is also applied in order to conclude that said experiment was successful and the results reliable. This test is acceptable for evaluation if the following criteria are satisfied: 1) Virus must be recovered from all dilutions of the Neutralizer Effectiveness/Viral Interference control that exhibit no cytotoxicity, 2) Virus must not be detected in the Cytotoxicity control or Cell Viability control, 3) The Cell Viability/Media sterility controls must exhibit viable cells at the conclusion of the test. In all instances the test results adhered to this Test Acceptance Criteria. Taken together, these quality controls determine with certainty that the results gained through biological testing are representative, accurate and reliable.

The following test illustrates how these controls have been appropriately applied to each test conducted for the BioFriend™ BioMask™ surgical facemask in order to elucidate the anti-influenza efficacy, and also demonstrates the recovery of all virus particles – both active infectious and inactivated – by the BioFriend™ BioMask™ surgical facemask following influenza challenge.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

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[redacted]

Based on the above question, the virucidal efficacy of the BioFriend™ BioMask™ surgical facemask against the three viruses Influenza B/Brisbane/60/2008, Influenza A/Hong Kong/8/68, Influenza A/Victoria/3/75, requires re-testing using higher titer stock. Due to the unavailability of virus, and in the interests of expediency, these viruses have therefore been removed from the labeling and indications of the device. Should these viruses be re-tested and the virucidal performance data be unequivocally demonstrated, a special 510(k) will be submitted to the FDA, requesting their inclusion.

As expected within any experimental system, non-specific loss of virus was observed for the BioFriend™ BioMask™ surgical facemask testing, accounted for by standard loss through processing, non-specific binding in facemask materials (≤10%, supported by the qRT-PCR testing results presented in Questions 28 and 31) but most significantly by MDCK host-cell cytotoxicity resulting from exposure to copper and zinc ions. The latter resulted in a simulated 1-2 log loss in the "window" available for the demonstration of influenza virus inactivation. These factors highlight the necessity to use high challenge inoculum and an appropriate extraction/neutralizer medium in the assays as

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filligent

K101128/S3
HOIDAGID

May 20, 2011

MAY 23 2011

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information - 510(k) Premarket Notification – K101128

This letter constitutes Filligent (HK) Limited's response to CDRH's request for additional information, which was received by email on March 7, and March 16, 2011. It represents our formal submission subsequent to our previous official submissions to date – namely:

- 510(k) Premarket Notification, dated April 20, 2010
- Additional Information, dated June 4, 2010 submitted in response to CDRH's request for additional information, which was dated and received by email on April 28, 2010
- Additional Information, dated November 13, 2010 submitted in response to CDRH's request for additional information, which was dated May 21, 2010
- Additional Information, dated February 19, 2011, submitted in response to CDRH's request for additional information, which was dated December 29, 2010
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With reference to our phone call with the FDA on 17 March 2011, we are submitting the results for the extended exposure test.

Secondly, in reference to Question 22 in the February 19, 2011 submission, we present the shelf life studies supporting a one year shelf-life.

Finally, as per the agency's request regarding the test results, we are submitting revised product labeling, which includes an additional cautionary statement with respect to mask soiling. The labeling also includes a one year shelf-life expiry date.

We believe that this response will provide adequate information to reach a determination of substantial equivalence. Nevertheless, if you require additional information, please do not hesitate to contact us at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Facsimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

K-2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent
creating
global health choices

May 20, 2011

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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7th Floor, 69 Jervois Street
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Telephone: +852 2542 2400
Facsimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

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1.0 Extended Exposure Testing of the BioFriend™ BioMask™ Surgical Facemask

2.0 Shelf-Life Testing

3.0 Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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SECTION 1:
Extended Exposure Testing of the BioFriend™ BioMask™ Surgical Facemask

CDRH Questions

You did not provide simulated-use testing that addressed the following issues. This information should be provided for consistency with similar devices containing antimicrobial properties/claims:

The justification provided to address our request for repeated challenge testing of the mask with in-use soil conditions was not adequate. High humidity storage conditions have not been demonstrated to have the same effect as in-use exhalent on antiviral performance. It is not clear what level of soiling or moisture would be considered a practical limit before the mask should be discarded and replaced, so the provided testing should address and justify the use conditions as appropriate for worst case. Please include testing that demonstrates the performance of the device under soil conditions that are reflective of the worst-case conditions for use of the device. The worst-case conditions should be explained and justified. Please contact the reviewer for additional clarification of this request.

The provided testing did not evaluate repeated viral challenges. This information should be provided to evaluate device performance over the entire use period and demonstrate the effect of numerous challenges on the effectiveness of the antiviral mask properties. Please provide simulated use testing that addresses the performance of the device against repeated challenges of virus using a subject of the claimed influenza viruses. Please justify your choices of viruses and ensure that the test condition appropriately reflect the worst case conditions for use of the device. The worst-case conditions should be explained and justified. Please contact the reviewer for additional clarification of this request.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

SECTION 3 LABELLING:

As per the agency's request, we are submitting the revised labeling which includes the additional warning statement: "If mask becomes soiled please change to a new mask as the anti-microbial agents may not be effective."

Following the results of the Shelf-Life testing, we have also revised the labeling to include a 12 month (one year) expiration date from the date of manufacture.

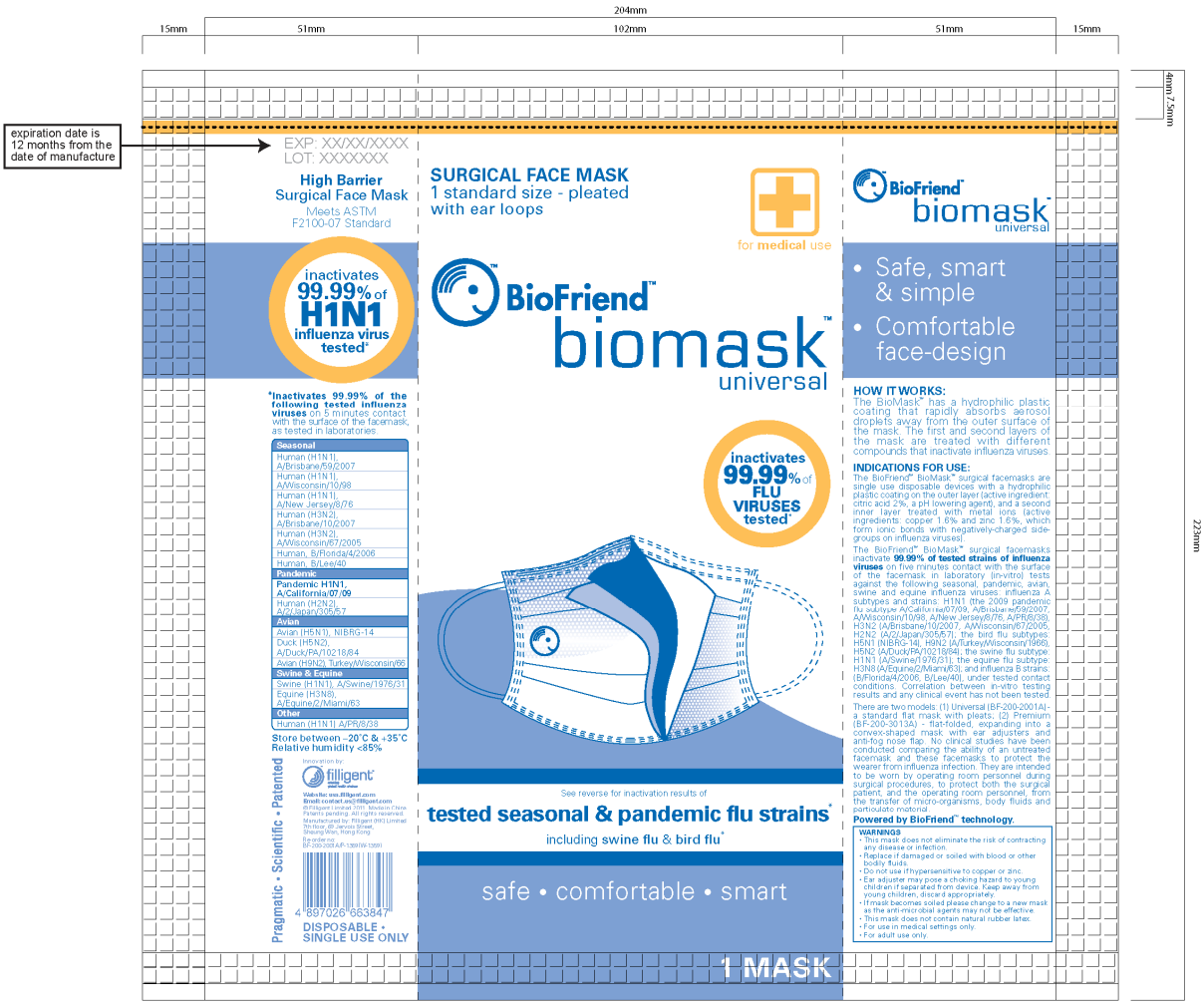
The revised labeling is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Bag

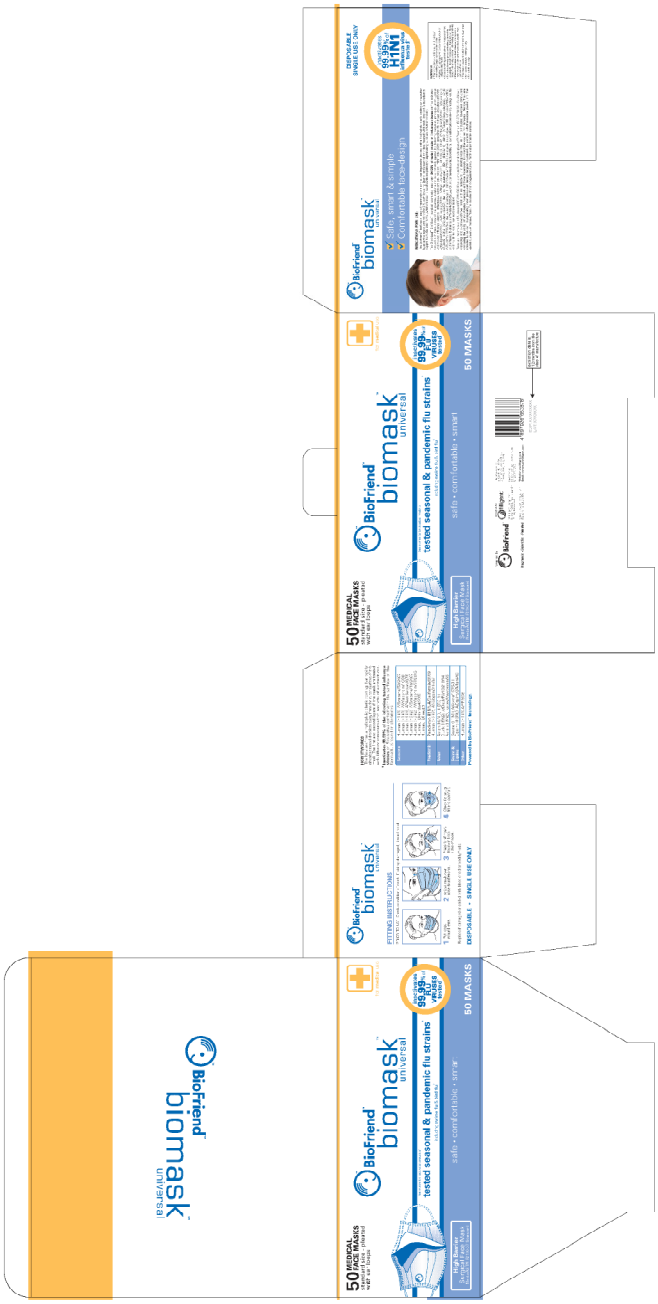


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Box – Complete

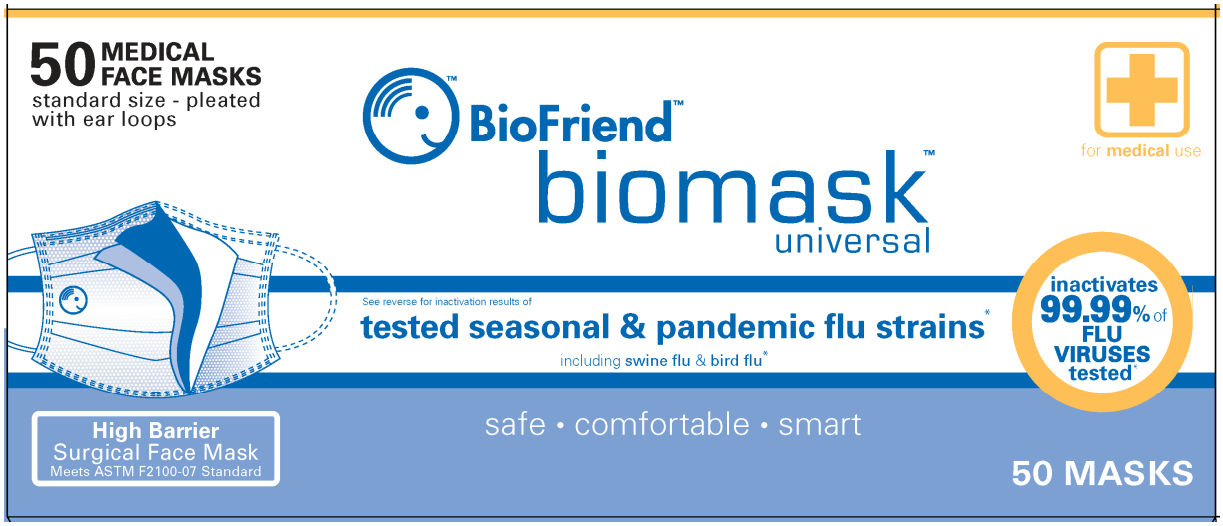


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

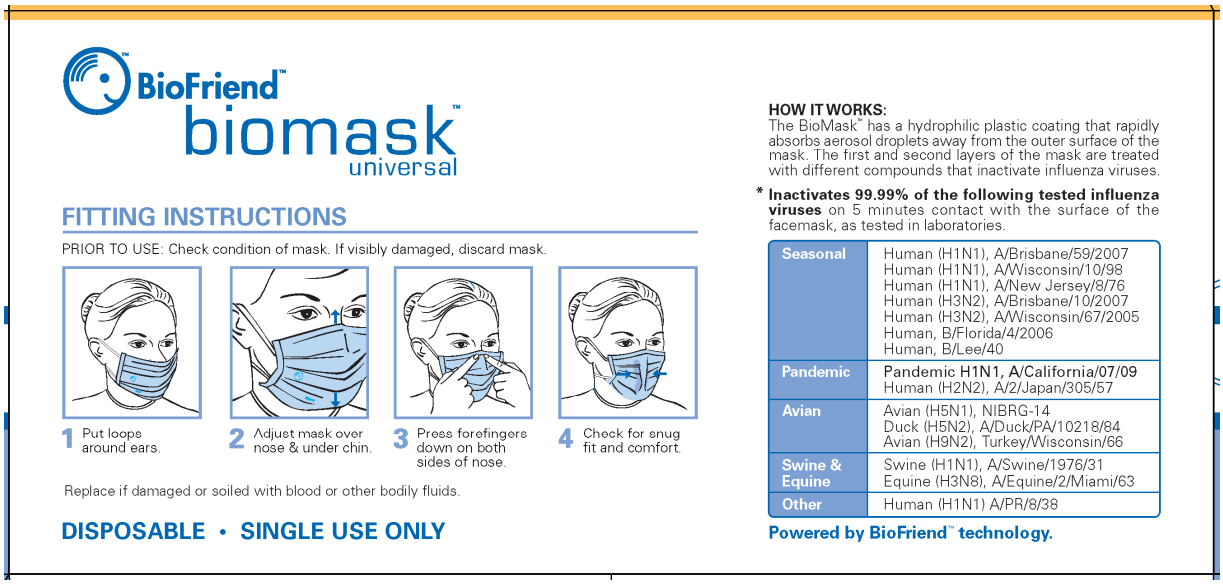
BioFriend™ BioMask™ Model: Universal BF-200-2001A

Box – Front and Back Panel



BioFriend™ BioMask™ Model: Universal BF-200-2001A

Box – Side Panel 1



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

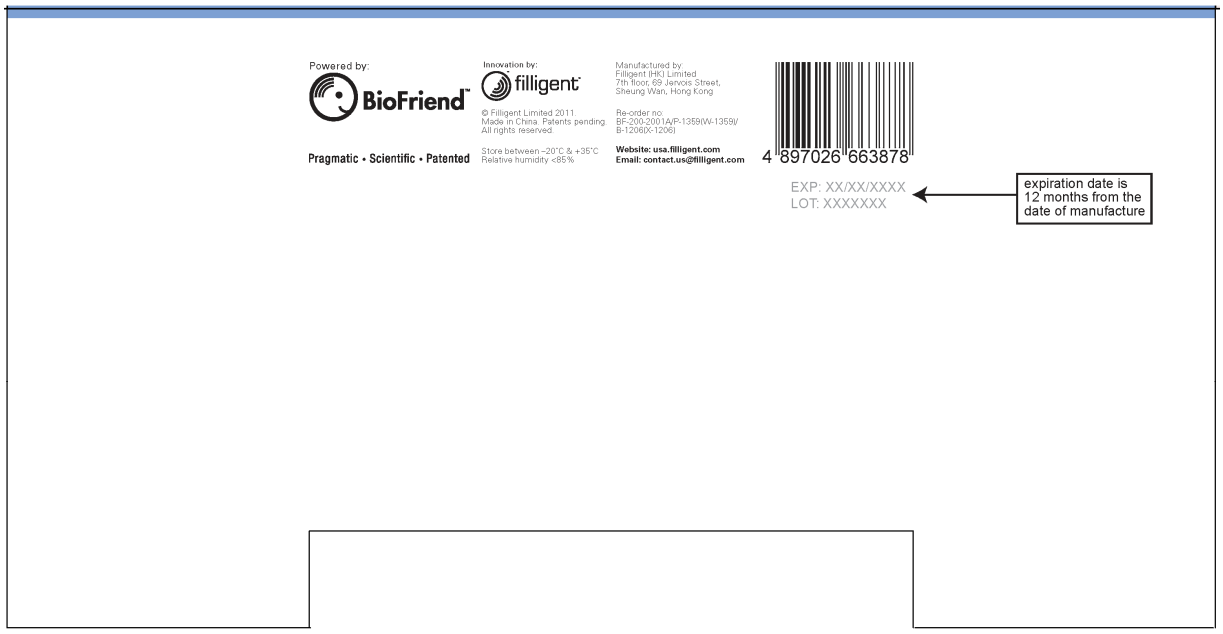
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Box – Side Panel 2

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Box – Bottom Flap

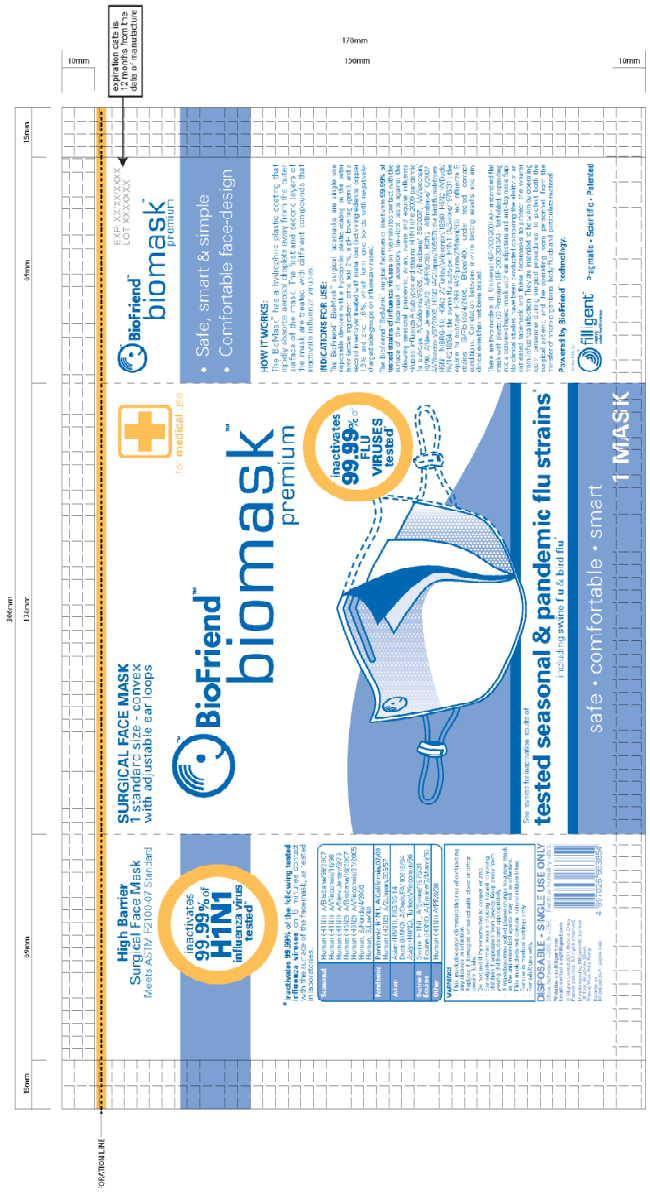


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Premium BF-200-3013A

Bag

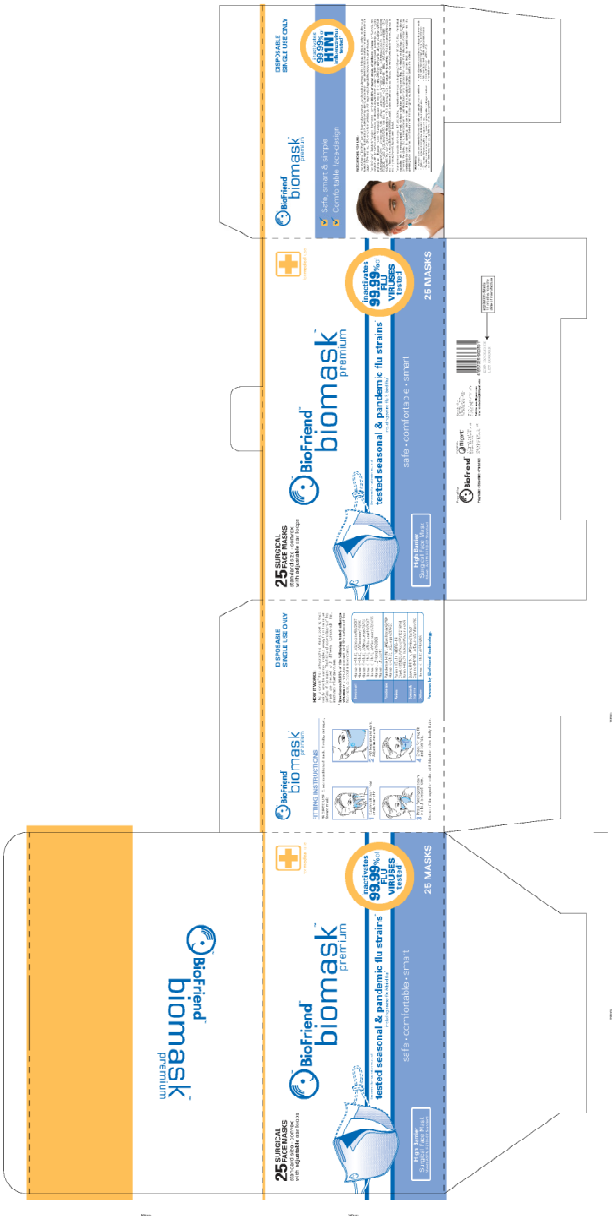


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Premium BF-200-3013A

Box – Complete



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

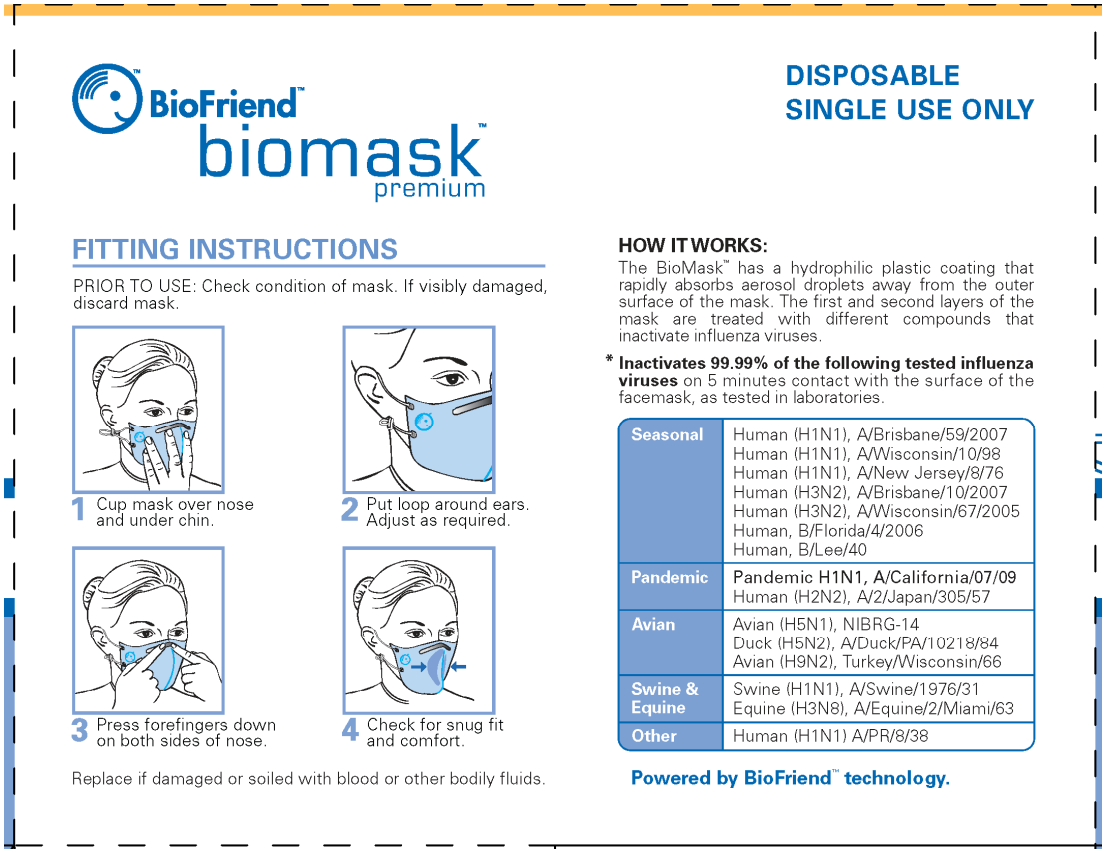
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Premium BF-200-3013A

Box – Front and Back Panel

BioFriend™ BioMask™ Model: Premium BF-200-3013A

Box – Side Panel 1



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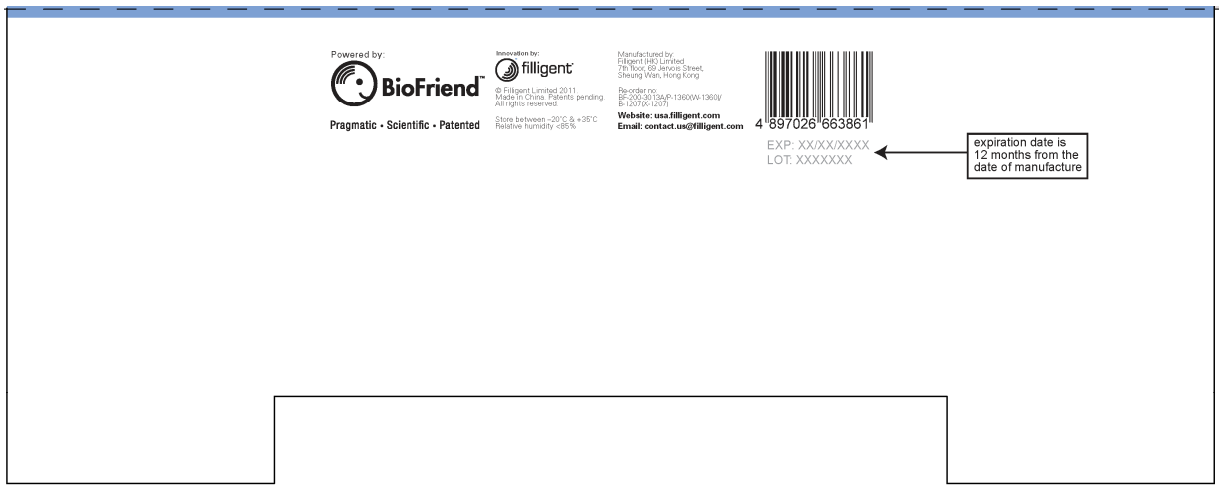
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Premium BF-200-3013A

Box – Side Panel 2

BioFriend™ BioMask™ Model: Premium BF-200-3013A

Box – Bottom Flap



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

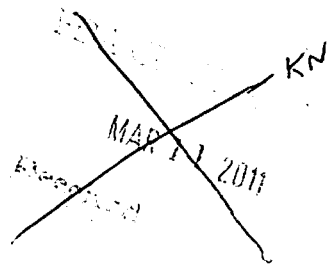
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016

K101128 | S3

FDA CDRH DMC

MAR 14 2011

Received



March 11, 2011

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information - 510(k) Premarket Notification – K101128

This letter constitutes Filligent (HK) Limited's response to CDRH's request for additional information; which was received by email on March 8, 2011, and dated March 7, 2011. It forms part of our total submissions to date – namely:

- 510(k) Premarket Notification, dated April 20, 2010
- Additional Information, dated June 4, 2010 submitted in response to CDRH's request for additional information, which was dated and received by email on April 28, 2010
- Additional Information, dated November 13, 2010 submitted in response to CDRH's request for additional information, which was dated May 21, 2010
- Additional Information, dated February 19, 2011, submitted in response to CDRH's request for additional information, which was dated December 29, 2010
- Additional information, which was dated March 2, 2011, submitted in response to the CDRH's request for additional information dated February 22 and February 25, 2011.

Each request is listed in the following pages, together with our response.

We believe that this response will provide adequate information to reach a determination of substantial equivalence. Nevertheless, if you require additional information, please do not hesitate to contact us at:

Filligent (HK) Limited

7th Floor, 69 Jervois Street

Sheung Wan, Hong Kong

Telephone: +852 2542 2400

Facsimile: +852 2542 2411

Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

K-17

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

filligent
creating
global health choices

March 11, 2011

Document Mail Center - WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Additional Information - 510(k) Premarket Notification – K101128

This letter constitutes Filligent (HK) Limited's response to CDRH's request for additional information, which was received by email on March 8, 2011, and dated March 7, 2011. It forms part of our total submissions to date – namely:

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Each request is listed in the following pages, together with our response.

We believe that this response will provide adequate information to reach a determination of substantial equivalence. Nevertheless, if you require additional information, please do not hesitate to contact us at:

Filligent (HK) Limited

7th Floor, 69 Jervois Street

Sheung Wan, Hong Kong

Telephone: +852 2542 2400

Facsimile: +852 2542 2411

Email: melissa@filligent.com

Sincerely

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

CDRH Questions

1. You provided an Indications-For-Use Statement, 510(k) Summary and labeling that use the term "kill" for viruses. The FDA believed that this term is not acceptable for viruses. Please provide an amended Indications-for-Use Statement, 510(k) and labeling that removes the term "kill" and only uses the term "inactivate."

2. FDA has released a new product code for the subject device. Please amend the 510(k) Summary by removing the FXX product code and replace it with our OUK.

3. You have not provided testing that fully addresses the use conditions of the subject device. You provided leach-off data with simulated salivary contact, but the antiviral performance of the subject device for extended use with soil and/or saliva on the surface of the mask and repeated viral challenges has not been determined. Please demonstrate whether the subject device is able to sustain antibacterial (antiviral) effectiveness over a period of time during use of the device. Will this level of performance be maintained over the expected use life of this device, which may be several hours? Since the claimed antiviral agents used in and on the surface of the masks that are the subject of this submission have never been approved by CDER as a drug, FDA has no data on the stability of antiviral performance of these compounds during use. Please provide detailed protocol of the evaluation of the subject mask surfaces against repeated challenge with the claimed influenza virus strains. Please ensure that the performance addresses performance of the mask with appropriate repeated viral challenges and soil conditions that could be expected during use.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

1. You provided an Indications-For-Use Statement, 510(k) Summary and labeling that use the term "kill" for viruses. The FDA believed that this term is not acceptable for viruses. Please provide an amended Indications-for-Use Statement, 510(k) and labeling that removes the term "kill" and only uses the term "inactivate."

The term "kill" has been removed from the Indications for Use/Statement of Intended Use, the Indications for Use/Statement of Intended Use section of the 510(k) Summary, and the labeling, and replaced with either the term "inactivate" or "inactivates" depending on the grammatical context.

The amended Indications-for-Use statement, 510(k) summary and labeling is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

2. FDA has released a new product code for the subject device. Please amend the 510(k) Summary by removing the FXX product code and replace it with our OUK.

The FXX product code has been removed from the 510 (k) Summary and replaced with the OUK product code.

The amended 510(k) Summary is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

4 Indications for Use Statement

510(k) Number:

K101128.

Device Name:

BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A and Premium BF-200-3013A

Indications for Use:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2% w/w, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% w/w and zinc 1.6% w/w, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks inactivate 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007,A/Wisconsin/67/2005,), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

Prescription Use _____ AND/OR Over-The Counter Use ___X___
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded and expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of microorganisms, body fluids and particulate material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5 510(k) Summary

5.1 Applicant and Correspondent

Name: Filligent (HK) Limited

Address: 7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

Contact Person: Melissa Mowbray-d'Arbela
Chief Executive Officer

Phone: (852) 2542 2400

Date of Preparation: March 11, 2011

5.2 Manufacturer

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan
Hong Kong

5.3 Name of Device

Trade/Proprietary/Model Name: BioFriend™ BioMask™ Surgical Facemask
Models: Universal BF-200-2001A
Premium BF-200-3013A

Common Name: Surgical Facemask

Classification Name: Mask, Surgical

Classification Regulation: 878.4040

Panel: General Hospital

Product Code: OUK

Recognized Performance Std: ASTM F2100-07 (refer to submission)

5.4 Devices to Which New Device is Substantially Equivalent

Device Name: Prestige Ameritech Face Mask
Manufacturer: Prestige Ameritech
Reference: K061716

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.5 Device Description

The BioFriend™ BioMask™ surgical facemask is offered in two mask styles, Model: BF-200-2001A ("Universal") and Model: BF-200-3013A ("Premium"). The Universal model is a standard flat mask with pleats, while the Premium model is flat-folded and expands into a convex-shaped mask. The Premium model also has ear adjusters and an anti-fog nose flap. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in these devices are typical construction materials commonly used in surgical facemasks and are being used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second inner layer is treated with copper and zinc. Both layers inactivate influenza viruses using different mechanisms of action. Masks are held in place on the wearer with elastic loops and contain a malleable metal nosepiece strip.

5.6 Statement of Intended Use

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks inactivate 99.99% of Influenza viruses on five minutes contact with the surface of the facemask in laboratory (*in vitro*) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005), H2N2 (A/2/JAPAN/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and Influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in vitro testing results and any clinical event has not been tested.

There are two models: (1) Universal (BF-200-2001A) - is a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and an anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from Influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.7 Summary of Technological Characteristics

The BioFriend™ BioMask™ surgical facemasks have substantially equivalent filter and barrier properties as the predicate device, and conform to the recognized FDA consensus standard ASTM F2100-07 Standard Specification for Performance of Materials used in Medical Face Masks. Both models of the BioFriend™ BioMask™ surgical facemask are constructed from the same materials and layers, and are identical in all respects other than shape. The outer layer of both models is coated with a hydrophilic plastic that allows aerosolized droplets contacting the surface of the mask to be rapidly absorbed into the inner layers. Both the outer and second inner layers are treated with different compounds that independently inactivate viruses through different mechanisms of action. Laboratory *(in vitro)* test results demonstrate that the BioFriend™ BioMask™ surgical facemasks inactivate 99.99% (≥4-logs) of 15 different strains of Influenza A and B viruses, including the circulating 2009 pandemic H1N1, recent vaccine isolates, major reassortments and avian, swine and equine isolates after 5 minutes contact with the mask surface.

The BioFriend™ BioMask™ surgical facemasks have been tested for, and appropriately passed standardized tests for, fluid penetration resistance, particulate filtration efficiency, bacterial filtration efficiency, flammability, and breathing resistance. The device as a whole has been shown to be biocompatible through standardized tests for irritation, sensitization and extractables.

The materials of construction used in the BioFriend™ BioMask™ surgical facemasks are equivalent to those of the predicate device. The devices as a whole are substantially equivalent to the predicate device.

5.8 Brief description of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

- Bacterial Filtration Efficiency – ASTM F2101
- Sub-micron Particulate Filtration Efficiency – ASTM F2299
- Fluid Penetration Resistance – ASTM F1862
- Breathing Resistance – MIL-M-3654C
- Flammability Testing – 16 CFR 1610
- Biocompatibility, Irritation – ISO 10993-10
- Biocompatibility, Sensitization – ISO 10993-10
- Biocompatibility, Chemical Characterization – ISO 10993-18

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

5.9 Brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Not applicable.

5.10 Conclusions drawn from the nonclinical and clinical tests

Standardized testing has shown that the construction materials used in both models of the BioFriend™ BioMask™ surgical facemask are substantially equivalent to those of the predicate device. The devices as a whole have been demonstrated to be biocompatible through irritation and sensitization testing, with toxicological assessment of the devices' components which could potentially be released with inhalation or salivary contact, indicating the devices are safe for use in the intended application. Laboratory testing has demonstrated the devices' efficacy. Both models of the BioFriend™ BioMask™ surgical facemask have been shown to be substantially equivalent to the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

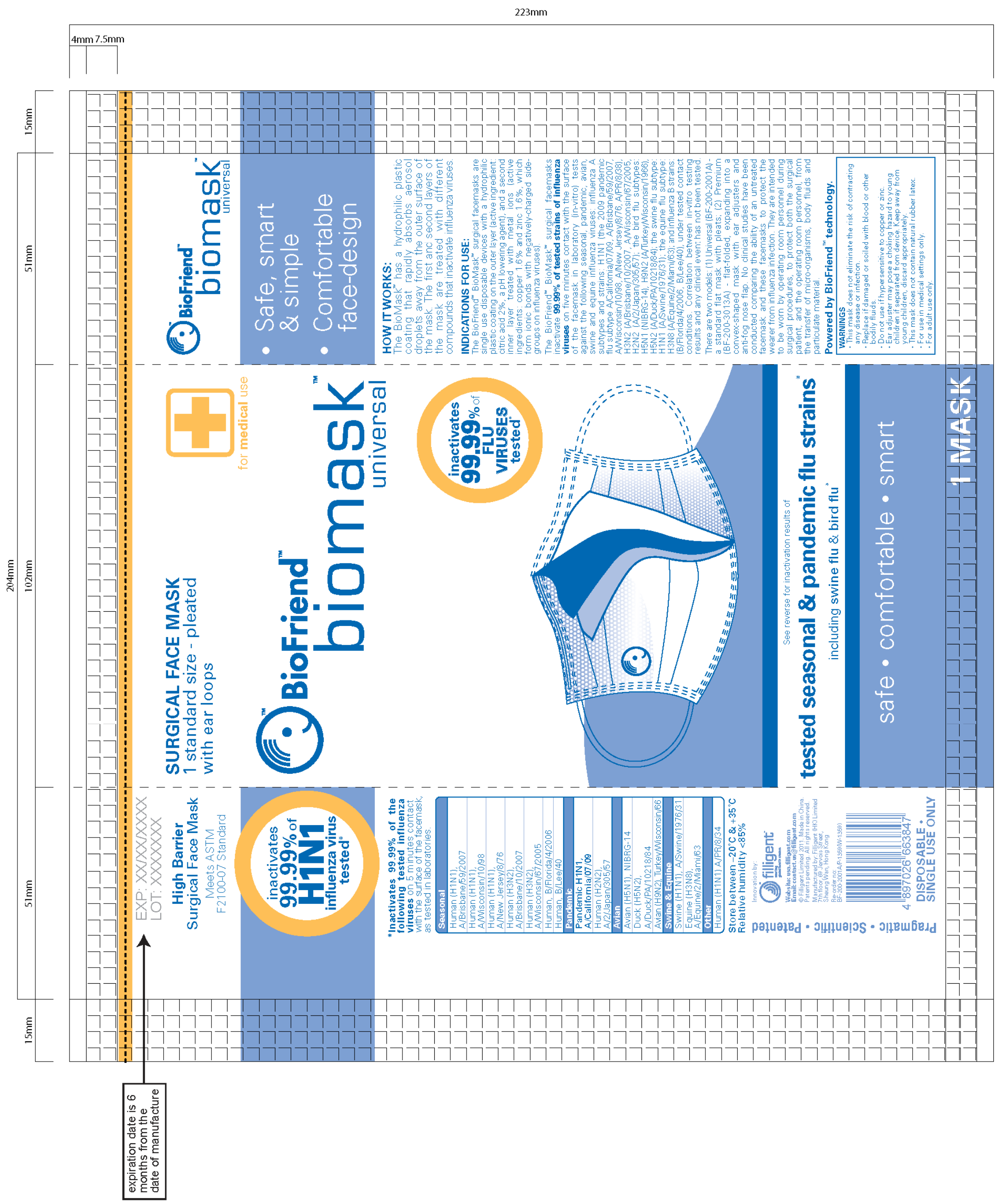
Labeling

In reference to CDRH Question 1, at the request of the FDA, the revised labeling for the BioFriend™ BioMask™ surgical facemask is provided in the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Bag – Principle Display Panel - Front & Reverse

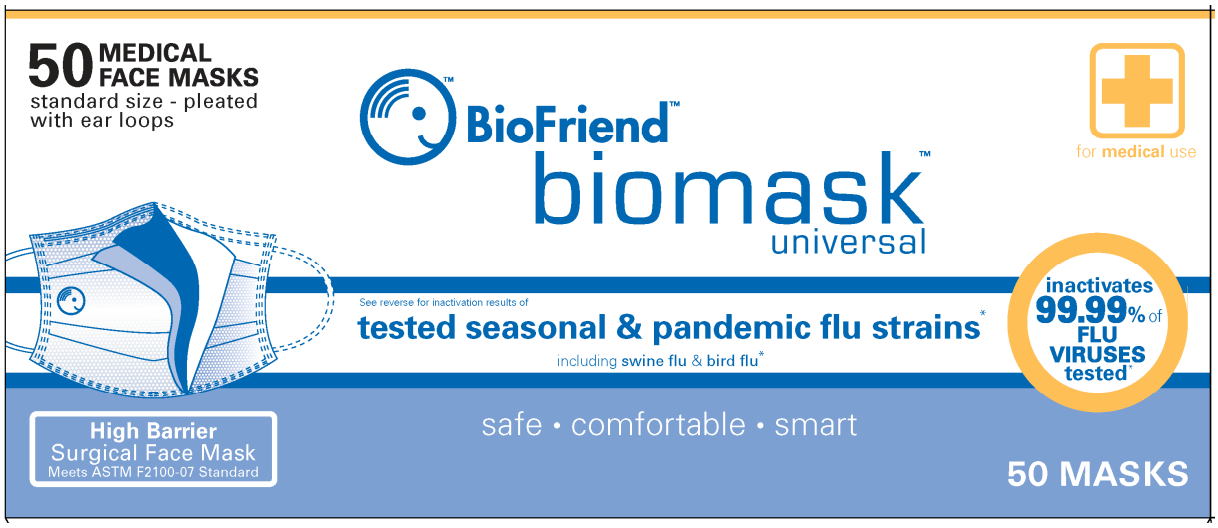


Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-2001A

Complete Box

Box - Principal Display Panel – Front & Reverse



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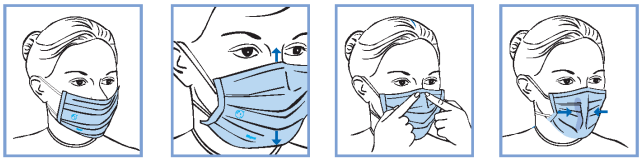
Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box - Side Panel 1

BioFriend™
biomask™
universal

FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask.



1 Put loops around ears.
2 Adjust mask over nose & under chin.
3 Press forefingers down on both sides of nose.
4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

DISPOSABLE • SINGLE USE ONLY

HOW IT WORKS:
The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the outer surface of the mask. The first and second layers of the mask are treated with different compounds that inactivate influenza viruses.

* **Inactivates 99.99% of the following tested influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal	Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human, B/Florida/4/2006 Human, B/Lee/40
Pandemic	Pandemic H1N1, A/California/07/09 Human (H2N2), A/2/Japan/305/57
Avian	Avian (H5N1), NIBRG-14 Duck (H5N2), A/Duck/PA/10218/84 Avian (H9N2), Turkey/Wisconsin/66
Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

Powered by BioFriend™ technology.

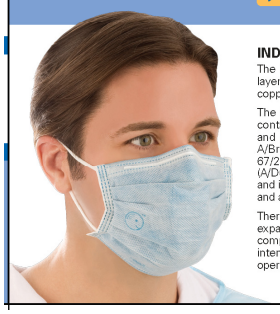
Box – Side Panel 2

BioFriend™
biomask™
universal

DISPOSABLE
SINGLE USE ONLY

inactivates **99.99%** of **H1N1** influenza virus tested*

- Safe, smart & simple
- Comfortable face-design



INDICATIONS FOR USE:
The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks kill inactivate **99.99% of tested strains of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, H2N2 (A/2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in-vitro testing results and any clinical event has not been tested.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

WARNINGS
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- Do not use if hypersensitive to copper or zinc.
- Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately.
- This mask does not contain natural rubber latex.
- For use in medical settings only.
- For adult use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Box – Lid

Box – Bottom

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

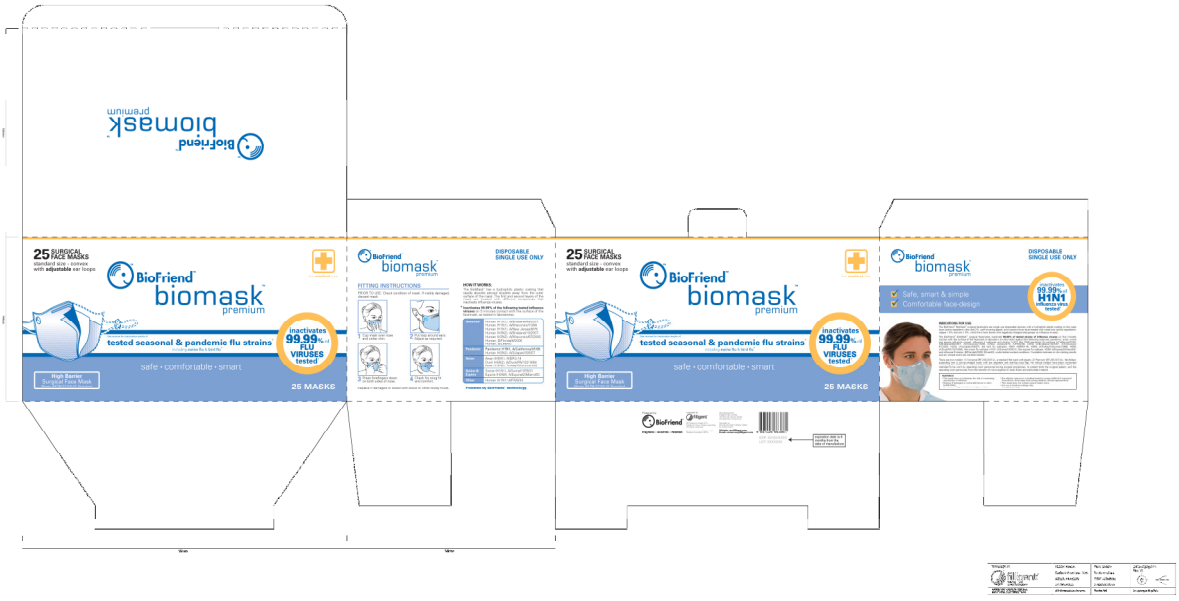
BioFriend™ BioMask™ Model: Universal BF-200-3013A

Bag - Principal Display Panel – Front & Reverse

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

BioFriend™ BioMask™ Model: Universal BF-200-3013A

Complete Box



Box - Principal Display Panel – Front & Reverse

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box - Side Panel 1

BioFriend™
biomask™
premium

DISPOSABLE
SINGLE USE ONLY

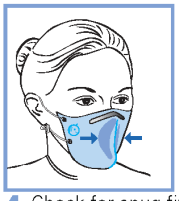
FITTING INSTRUCTIONS

PRIOR TO USE: Check condition of mask. If visibly damaged, discard mask.

1 Cup mask over nose and under chin.

2 Put loop around ears. Adjust as required.

3 Press forefingers down on both sides of nose.



4 Check for snug fit and comfort.

Replace if damaged or soiled with blood or other bodily fluids.

HOW IT WORKS:

The BioMask™ has a hydrophilic plastic coating that rapidly absorbs aerosol droplets away from the outer surface of the mask. The first and second layers of the mask are treated with different compounds that inactivate influenza viruses.

* **Inactivates 99.99% of the following tested influenza viruses** on 5 minutes contact with the surface of the facemask, as tested in laboratories.

Seasonal	Human (H1N1), A/Brisbane/59/2007 Human (H1N1), A/Wisconsin/10/98 Human (H1N1), A/New Jersey/8/76 Human (H3N2), A/Brisbane/10/2007 Human (H3N2), A/Wisconsin/67/2005 Human, B/Florida/4/2006 Human, B/Lee/40
Pandemic	Pandemic H1N1, A/California/07/09 Human (H2N2), A/2/Japan/305/57
Avian	Avian (H5N1), NIBRG-14 Duck (H5N2), A/Duck/PA/10218/84 Avian (H9N2), Turkey/Wisconsin/66
Swine & Equine	Swine (H1N1), A/Swine/1976/31 Equine (H3N8), A/Equine/2/Miami/63
Other	Human (H1N1) A/PR/8/34

Powered by BioFriend™ technology.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

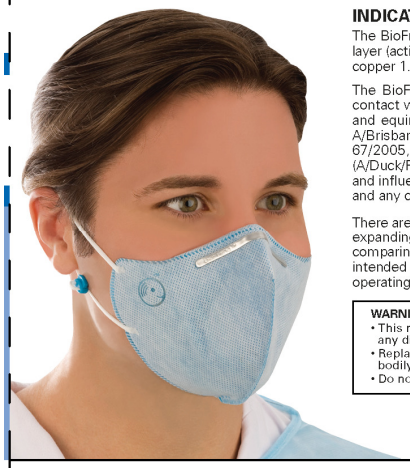
Box – Side Panel 2

BioFriend™
biomask™
premium

DISPOSABLE
SINGLE USE ONLY

- Safe, smart & simple
- Comfortable face-design

inactivates 99.99% of H1N1 influenza virus tested*



INDICATIONS FOR USE:

The BioFriend™ BioMask™ surgical facemasks are single use disposable devices with a hydrophilic plastic coating on the outer layer (active ingredient: citric acid 2%, a pH lowering agent), and a second inner layer treated with metal ions (active ingredients: copper 1.6% and zinc 1.6%, which form ionic bonds with negatively-charged side-groups on influenza viruses).

The BioFriend™ BioMask™ surgical facemasks inactivate **99.99% of tested strains of influenza viruses** on five minutes contact with the surface of the facemask in laboratory (in-vitro) tests against the following seasonal, pandemic, avian, swine and equine influenza viruses: influenza A subtypes and strains: H1N1 (the 2009 pandemic flu subtype A/California/07/09, A/Brisbane/59/2007, A/Wisconsin/10/98, A/New Jersey/8/76, A/PR/8/38), H3N2 (A/Brisbane/10/2007, A/Wisconsin/67/2005, H2N2 (A/2/Japan/305/57); the bird flu subtypes: H5N1 (NIBRG-14), H9N2 (A/Turkey/Wisconsin/1966), H5N2 (A/Duck/PA/10218/84); the swine flu subtype: H1N1 (A/Swine/1976/31); the equine flu subtype: H3N8 (A/Equine/2/Miami/63); and influenza B strains: (B/Florida/4/2006, B/Lee/40), under tested contact conditions. Correlation between in-vitro testing results and any clinical event has not been tested.

There are two models: (1) Universal (BF-200-2001A) - a standard flat mask with pleats; (2) Premium (BF-200-3013A) - flat-folded, expanding into a convex-shaped mask with ear adjusters and anti-fog nose flap. No clinical studies have been conducted comparing the ability of an untreated facemask and these facemasks to protect the wearer from influenza infection. They are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient, and the operating room personnel, from the transfer of micro-organisms, body fluids and particulate material.

WARNINGS

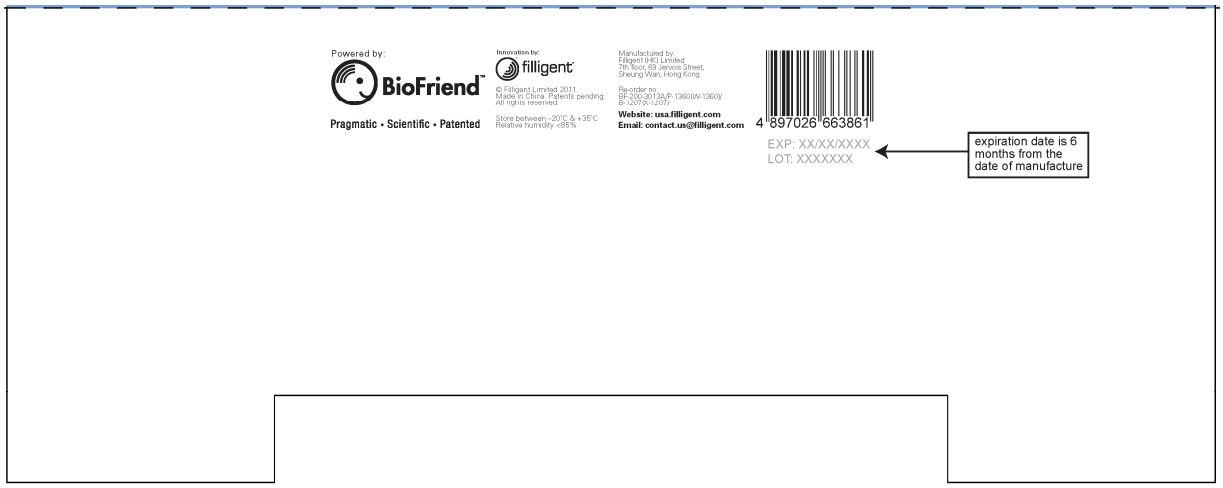
- This mask does not eliminate the risk of contracting any disease or infection.
- Replace if damaged or soiled with blood or other bodily fluids.
- Do not use if hypersensitive to copper or zinc.
- Ear adjuster may pose a choking hazard to young children if separated from device. Keep away from young children, discard appropriately.
- This mask does not contain natural rubber latex.
- For use in medical settings only.
- For adult use only.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Box – Lid

Box – Bottom



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

3. You have not provided testing that fully addresses the use conditions of the subject device. You provided leach-off data with simulated salivary contact, but the antiviral performance of the subject device for extended use with soil and/or saliva on the surface of the mask and repeated viral challenges has not been determined. Please demonstrate whether the subject device is able to sustain antibacterial (antiviral) effectiveness over a period of time during use of the device. Will this level of performance be maintained over the expected use life of this device, which may be several hours? Since the claimed antiviral agents used in and on the surface of the masks that are the subject of this submission have never been approved by CDER as a drug, FDA has no data on the stability of antiviral performance of these compounds during use. Please provide detailed protocol of the evaluation of the subject mask surfaces against repeated challenge with the claimed influenza virus strains. Please ensure that the performance addresses performance of the mask with appropriate repeated viral challenges and soil conditions that could be expected during use.

Based on existing testing, the BioFriend™ BioMask™ surgical facemask sustains full (>4-log) virus-inactivating effectiveness over the anticipated duration and conditions of use. The viral load used for testing and demonstration of inactivation of the 15 different influenza virus strains far exceeds viral loads that would be expected to contact the facemask during anticipated use. The BioFriend™ BioMask™ surgical facemask has been demonstrated to retain >4-log inactivation of tested viruses when kept for 6 months under temperature and humidity conditions more extreme than those to which the facemask is likely to be exposed during a period of only several hours of use.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

From the above, the capacity of the virus-inactivating constituents of the BioFriend™ BioMask™ surgical facemask will therefore not be saturated by virus or liquid to which it might be exposed during actual use in a healthcare environment, as it can inactivate viral loads several orders of magnitude higher than could be realistically found in aerosolized droplets.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Furthermore, the BioFriend™ BioMask™ surgical facemask is disposable, and one of the warnings on the device's labeling, is the statement "Replace if damaged or soiled with blood or other bodily fluids". This warns against continued wear following excessive soiling on occasions when the mask is exposed to a large volume of fluid.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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filligent
creating
global health choices

K101128/A002

May 25, 2010

Document Mail Center – WO66-0609
FDA/CDRH Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAY 26 2010
Received

Attention: Dr Sheila Murphey and Mr Steven Elliott

Dear Dr. Murphey, Mr Elliott

Re: Supplement to 510(k) Premarket Notification – K101128

Our firm submitted a 510(k) premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128) on Thursday April 22, 2010. On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Medical Officer, Infection Control Devices Branch, was received requesting Filligent to provide further information (the ***FDA Request***). Our supplementary response has been in two stages. The first stage was submitted on Tuesday, May 4, 2010 and addressed questions 4 to 10 of the FDA Request (a copy of which is attached for easy reference). We hereby enclose the second stage to our supplementary response, which addresses the remaining queries of the FDA Request, namely questions 1 to 3 inclusive.

Should you require any additional data in order to reach a determination of substantial equivalence, please do not hesitate to contact me at:

Filligent (HK) Limited
7th Floor, 69 Jervois Street
Sheung Wan, Hong Kong
Telephone: +852 2542 2400
Fascimile: +852 2542 2411
Email: melissa@filligent.com

Sincerely

K16

Melissa Mowbray-d'Arbela
Chief Executive Officer
Filligent (HK) Limited

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

242

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Supplementary Response to FDA Request

Our firm has submitted a premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128, the "510(k) Submission"). On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Infection Control Devices Branch, was received requesting Filligent to provide further information:

As we review your 510(k) submission, it is very important that we have a complete description of the antimicrobial agents in the Filligent BioMasks and how they interact with each other and their safety for wearers of the devices. Please provide the following information, either with respect to its current location in the file or as additional information (we have looked for these items and could not find them):

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

10. Please state whether or not any "anti-fog" compound has been added to the polyurethane nose sponge on the Premium BF 200-3013 mask or where it is the presence of untreated polyurethane which is considered to provide the anti-fog function

If the above information is not already in the file, please provide it to Mr. Elliott and to me electronically as soon as you can. Please also send a copy of this material to the Document mail Center so that it can be officially added to the contents of your file.

We may have additional questions later as we proceed with this review. If that is the case, we will send them to you. We expect to request consultation from the Center for Drug Evaluation and Research (CDER) on this interesting submission. However, we must be sure before we place the request that all of the information which CDER will need will be available in the file. If you have any questions about the information needed, please let me know.

Thank you very much for your assistance in providing this information.

Regards,
Sheila A. Murphey, MD

. . . . . .

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

2. The acceptance criteria for the pH of the outer layer of your devices

See response to Question 1.

3. The pH of the second layer of your devices when the aerosols contacting the outer layer are "drawn into" the second layer

See response to Question 1.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

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(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

The MSDS sheets for the remaining chemical constituents of the BioFriend™ BioMask™ are provided in Appendix 2:

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

6. Please provide the levels of citric acid, copper and zinc in your devices by ugm or mgm per unit of area such as cm^2 for your devices

See response to Question 7.

7. Please provide the total amounts of citric acid, copper and zinc per total, complete device for each of your mask models

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. Both models are comprised of four layers of material: an outer layer of spun-bond polypropylene, a second layer of cellulose/ polyester, a third layer of melt-blown polypropylene filter material and an inner (fourth) layer of spun-bound polypropylene. All of the construction materials used in this device are typical construction materials commonly used in surgical face masks and are being

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used in current legally marketed devices. The outer layer is coated with a hydrophilic plastic. The second layer is treated with copper and zinc. Masks are held in place on the wearer with latex free elastic loops and contain a malleable metal nosepiece strip. One model is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard "comfort" features such ear adjusters and an anti-fog nose insert. The materials used in the construction of the Universal BF-200-2001 and (b) (4) [redacted] (also refer to Tables 15-4 and 15-5, page 15-4 of the 510(k) Submission). The minimum and maximum levels of the antimicrobial agents in the devices, as defined by the acceptance criteria, are also given.

Table 1 Summary of Antimicrobial Agent Composition of the BioFriend™ BioMask™ Surgical Facemasks

Material	% Composition of Layer (w/w)	Amount in Mask ($\mu g/cm^2$)[1]	Amount in Mask (mg)[1]
Outer Polypropylene Layer			
Citric Acid	(b) (4) [redacted]		
Cellulose/Poly			
Copper			
Zinc			

[1] Based on (b) (4) [redacted]
[2] min and max as calculated from the acceptance criteria

8. Please provide the dimensions and area for each of your two mask models

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. One is flat-folded and pleated to expand into a concertina-shaped mask (Universal BF-200-2001), while the other model is flat-folded along a central single fold to expand into a convex-shaped mask (Premium BF-200-3013). The Premium model also has certain standard "comfort" features such

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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ear adjusters and an anti-fog nose insert. The major dimensions for each device are summarized in Table 2, and Figures 1 and 2. Both the Universal BF-200-2001 and Premium BF-200-3013 contain

(b) (4)

[redacted]

Table 2 Major Dimensions of the BioFriend™ BioMask™ Surgical Facemasks

Major Dimensions	BioFriend™ BioMask™ Universal BF-200-2001	BioFriend™ BioMask™ Premium BF-200-3013

(b) (4)

[redacted]

Figure 1 Major Dimensions of the BioFriend™ BioMask™ Universal BF-200-2001

(b) (4)

[redacted]

(b) (4)

[redacted]

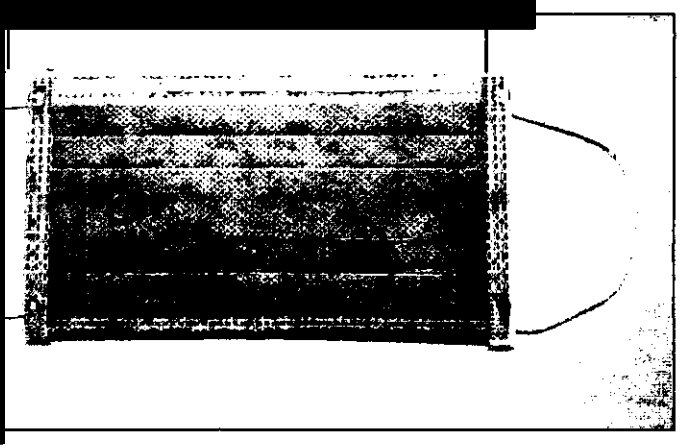

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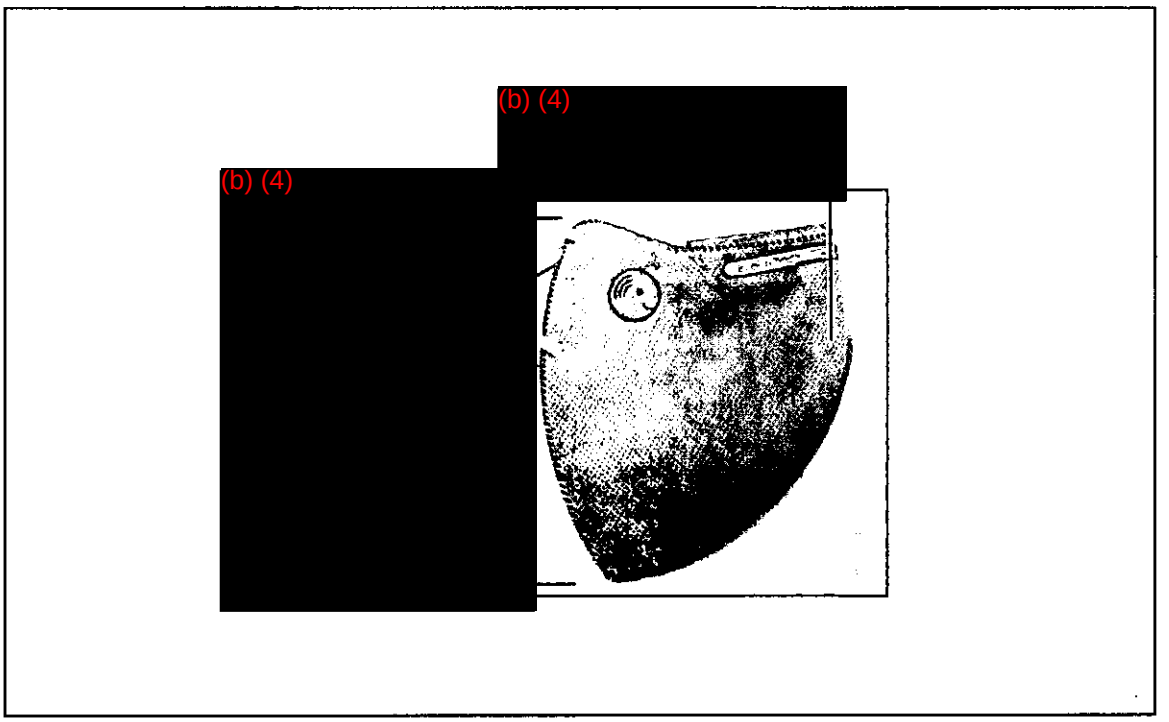
Figure 2 Major Dimensions of the BioFriend™ BioMask™ Premium BF-200-3013



9. Please identify the contribution of the copper in CI Reactive Blue 21 to the antimicrobialactivity of your device

(b) (4)

10. Please state whether or not any "anti-fog" compound has been added to the polyurethane nose sponge on the Premium BF 200-3013 mask or where it is the presence of untreated polyurethane which is considered to provide the anti-fog function

No "anti-fog" compounds have been added to the polyurethane sponge. The presence of untreated polyurethane on the inside of the nose-flap is used to improve seal of the nose-flap around the nose to help prevent glasses and face shields from fogging.

[1] Lawton, E. A. (1958) The thermal stability of copper phthalocyanine. *J. Phys. Chem.*62 (3): 384

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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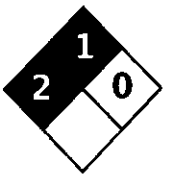
Appendix 1-A: Citric Acid MSDS



Health	2
Fire	1
Reactivity	0
Personal Protection	E

Material Safety Data Sheet
Citric acid MSDS

Section 1: Chemical Product and Company Identification

Product Name: Citric acid

Catalog Codes: SLC5449, SLC2665, SLC4453, SLC1660, SLC3451

CAS#: 77-92-9

RTECS: GE7350000

TSCA: TSCA 8(b) inventory: Citric acid

CI#: Not available..

Synonym: 2-Hydroxy-1,2,3-propanetricarboxylic acid

Chemical Name: Citric Acid

Chemical Formula: C6H8O7

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Citric acid	77-92-9	100

Toxicological Data on Ingredients: Citric acid: ORAL (LD50): Acute: 5040 mg/kg [Mouse]. 3000 mg/kg [Rat].

Section 3: Hazards Identification

Potential Acute Health Effects:
Hazardous in case of eye contact (irritant), of inhalation (lung irritant). Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion. The amount of tissue damage depends on length of contact. Eye contact can result in corneal damage or blindness. Skin contact can produce inflammation and blistering. Severe over-exposure can produce lung damage, choking, unconsciousness or death.

Potential Chronic Health Effects:
Slightly hazardous in case of skin contact (sensitizer).
CARCINOGENIC EFFECTS: Not available.
MUTAGENIC EFFECTS: Not available.
TERATOGENIC EFFECTS: Not available.
DEVELOPMENTAL TOXICITY: Not available.
The substance may be toxic to teeth.
Repeated or prolonged exposure to the substance can produce target organs damage. Repeated exposure of the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 253

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Appendix 1-A: Citric Acid MSDS

eyes to a low level of dust can produce eye irritation. Repeated skin exposure can produce local skin destruction, or dermatitis. Repeated inhalation of dust can produce varying degree of respiratory irritation or lung damage.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Skin Contact:
In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact:
Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: 1010°C (1850°F)

Flash Points: Not available.

Flammable Limits: LOWER: 0.28 Kg/M3 (Dust) UPPER: 2.29 Kg/M3 (Dust)

Products of Combustion: These products are carbon oxides (CO, CO2).

Fire Hazards in Presence of Various Substances:
Slightly flammable to flammable in presence of heat.
Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Slightly explosive in presence of open flames and sparks.
Non-explosive in presence of shocks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Appendix 1-A: Citric Acid MSDS

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Eliminate all ignition sources. Call for assistance on disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, reducing agents, metals, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:
Safety glasses. Lab coat. Gloves (impervious). Dust respirator. Be sure to use an approved/certified respirator or equivalent. The dust respirator should be used for conditions where exposure has exceeded recommended exposure limits, dust is apparent, and engineering controls(adequate ventilation) are not feasible.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:
No exposure guidelines have been established.
ACGIH, NIOSH and OSHA have not developed exposure limits for this product.
The exposure limits given below are for particulates not otherwise classified:
ACGIH: 10 mg/m3 TWA (Total Inhalable fraction); 3 mg/m3 TWA (Respirable fraction)
OSHA: 15 mg/m3 TWA (Total dust); 5 mg/m3 TWA (Respirable Fraction)

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Crystalline powde)

Odor: Odorless.

Taste: Acid. (Strong.)

Molecular Weight: 192.13 g/mole

Color: Not available.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118. 255

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Appendix 1-A: Citric Acid

pH (1% soln/water): Not available.

Boiling Point: Decomposes.

Melting Point: 153°C (307.4°F)

Critical Temperature: Not available.

Specific Gravity: 1.665 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: The product is more soluble in water; log(oil/water) = -1.7

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water, diethyl ether.

Solubility:
Soluble in cold water, hot water, diethyl ether.
Insoluble in benzene.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents, reducing agents, metals, alkalis.

Corrosivity:
Corrosive in presence of aluminum, of zinc, of copper.
Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Incompatible with oxidizing agents, potassium tartrate, alkali, alkaline earth carbonates and bicarbonates, acetates, and sulfides, metal nitrates

Special Remarks on Corrosivity: Will corrode copper, zinc, aluminum and their alloys.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 3000 mg/kg [Rat].

Chronic Effects on Humans: May cause damage to the following organs: teeth.

Other Toxic Effects on Humans:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Appendix 1-A: Citric Acid

Hazardous in case of inhalation (lung irritant).
Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion.

Special Remarks on Toxicity to Animals: LDL[Rabbit] - Route: oral; Dose: 7000mg/kg

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects:
Skin: Causes mild to moderate skin irritation. May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material.
Eyes: Causes moderate to severe eye irritation and possible injury.
Ingestion: May cause gastrointestinal (digestive) tract irritation with nausea, vomiting, diarrhea. Excessive intake may cause erosion of teeth and hypocalcemia (calcium deficiency in blood). May affect behavior/central nervous system (tremor, convulsions, muscle contraction or spasticity).
Inhalation: Causes moderate respiratory tract and mucous membrane irritation.
Chronic Potential Health Effects:
Frequent intake of citrated beverages may cause erosion of dental enamel and irritation of mucous membranes.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Citric acid

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): CLASS E: Corrosive solid.

DSCL (EEC):

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Appendix 1-A: Citric Acid

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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R36/37/38- Irritating to eyes, respiratory system and skin.
S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S37/39- Wear suitable gloves and eye/face protection.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: e

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves (impervious).
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate.
Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 04:56 PM

Last Updated: 11/06/2008 12:00 PM

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall ScienceLab.com be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if ScienceLab.com has been advised of the possibility of such damages.

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(b) (4)

MSDS Number: C5808 * * * * * *Effective Date: 08/17/09* * * * * *Supercedes: 10/16/06*

MSDS *Material Safety Data Sheet*

From: Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ

Mallinckrodt CHEMICALS

J.T.Baker

24 Hour Emergency Telephone:
CHEMTREC:

National Response in Canada
CANUTEC:

Outside U.S. and Canada
Chemtrec:

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-582-2537) for assistance.

(b) (4)

3. Hazards Identification

Emergency Overview

DANGER! CAUSES EYE BURNS. HARMFUL IF SWALLOWED. CAUSES IRRITATION TO SKIN AND RESPIRATORY TRACT.

SAF-T-DATA(tm) Ratings (Provided here for your convenience)

Health Rating: 2 - Moderate (Life)
Flammability Rating: 1 - Slight
Reactivity Rating: 1 - Slight
Contact Rating: 3 - Severe
Lab Protective Equip: GOGGLES & SHIELD; LAB COAT & APRON; VENT HOOD; PROPER GLOVES; CLASS D EXTINGUISHER
Storage Color Code: Green (General Storage)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b) (4) [redacted]

Potential Health Effects

Inhalation:
Causes irritation to respiratory tract, symptoms may include coughing, sore throat, and shortness of breath. May result in ulceration and perforation of respiratory tract. When heated, this compound may give off copper fume, which can cause symptoms similar to the common cold, including chills and stuffiness of the head.
Ingestion:
May cause burning pain in the mouth, esophagus, and stomach. Hemorrhagic gastritis, nausea, vomiting, abdominal pain, metallic taste, and diarrhea may occur. If vomiting does not occur immediately systemic copper poisoning may occur. Symptoms may include capillary damage, headache, cold sweat, weak pulse, kidney and liver damage, central nervous excitation followed by depression, jaundice, convulsions, blood effects, paralysis and coma. Death may occur from shock or renal failure.
Skin Contact:
May cause irritation with redness and pain.
Eye Contact:
Corrosive. May cause irritation, redness, pain, blurred vision, discoloration, and damage.
Chronic Exposure:
Prolonged or repeated skin exposure may cause dermatitis. Prolonged or repeated exposure to dusts of copper salts may cause discoloration of the skin or hair, blood and liver damage, ulceration and perforation of the nasal septum, runny nose, metallic taste, and atrophic changes and irritation of the mucous membranes.
Aggravation of Pre-existing Conditions:
Persons with pre-existing skin disorders, impaired liver, kidney, or pulmonary function, glucose 6-phosphate-dehydrogenase deficiency, or pre-existing Wilson's disease may be more susceptible to the effects of this material.

4. First Aid Measures

Inhalation:
Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.
Ingestion:
Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. Call a physician.
Skin Contact:
In case of contact, wipe off excess material from skin then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Call a physician.
Eye Contact:
Immediately flush eyes with gentle but large stream of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Call a physician immediately.

5. Fire Fighting Measures

Fire:
Not considered to be a fire hazard. May form combustible fumes upon decomposition which may increase the flammability of a fire.
Explosion:
Reactions with incompatibles may pose an explosion hazard.
Fire Extinguishing Media:
Use any means suitable for extinguishing surrounding fire. Water spray may be used to keep fire exposed containers cool.
Special Information:
In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

US Regulations (CERCLA) require reporting spills and releases to soil, water and air in excess of reportable quantities. The toll free number for the US Coast Guard National Response Center is (800) 424-8802. Ventilate area of leak or spill. Keep unnecessary and unprotected people away from area of spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Isolate from incompatible substances. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:
-OSHA Permissible Exposure Limit (PEL):
1 mg/m3 (TWA) for copper dusts & mists as Cu
-ACGIH Threshold Limit Value (TLV):
1 mg/m3 (TWA) for copper dusts & mists as Cu
Ventilation System:
A system of local and/or general exhaust is recommended to keep employee exposures below the Airborne Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.
Personal Respirators (NIOSH Approved):
If the exposure limit is exceeded and engineering controls are not feasible, a half facepiece particulate respirator (NIOSH type N95 or better filters) may be worn for up to ten times the exposure limit or the maximum use concentration specified by the appropriate regulatory agency or respirator supplier, whichever is lowest.. A full-face piece particulate respirator (NIOSH type N100 filters) may be worn up to 50 times the exposure limit, or the maximum use concentration specified by the appropriate regulatory agency, or respirator supplier, whichever is lowest. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-facepiece positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.
Skin Protection:
Wear protective gloves and clean body-covering clothing.
Eye Protection:
Use chemical safety goggles and/or full face shield where dusting or splashing of solutions is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:
Dark green powder.
Odor:
Slight acetic acid odor.
Solubility:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b) (4)

[redacted]

7.2 g/100 cc cold water; 20 g/100 cc hot water.
Density:
1.88
pH:
No information found.
% Volatiles by volume @ 21C (70F):
0
Boiling Point:
240C (464F) Decomposes.
Melting Point:
115C (239F)
Vapor Density (Air=1):
No information found.
Vapor Pressure (mm Hg):
No information found.
Evaporation Rate (BuAc=1):
No information found.

10. Stability and Reactivity

Stability:
Stable under ordinary conditions of use and storage.
Hazardous Decomposition Products:
May produce oxides of carbon and the contained metal.
Hazardous Polymerization:
Will not occur.
Incompatibilities:
Sodium hypobromite, acetylene, hydrazine, and nitromethane.
Conditions to Avoid:
Incompatibles.

11. Toxicological Information

(b) (4)

[redacted]

12. Ecological Information

Environmental Fate:
This material is expected to significantly bioaccumulate. This material has an experimentally-determined bioconcentration factor (BCF) of greater than 100. Bioaccumulation data for copper.
Environmental Toxicity:
This material is expected to be very toxic to aquatic life. The LC50/96-hour values for fish are less than 1 mg/l. The IC50/72-hour values for algae are less than 1 mg/l. Toxicity data for copper.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

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13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

(b) (4)

[redacted]

15. Regulatory Information

--------\Chemical Inventory Status - Part 1\--------

Ingredient	TSCA	EC	Japan	Australia

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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--------\Federal, State & International Regulations - Part 2\---------------
                                                      -RCRA-     -TSCA-
Ingredient                                  CERCLA    261.33      8(d)
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Australian Hazchem Code: None allocated.
Poison Schedule: None allocated.
WHMIS:
This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: **2** Flammability: **0** Reactivity: **0**
Label Hazard Warning:
DANGER! CAUSES EYE BURNS. HARMFUL IF SWALLOWED. CAUSES IRRITATION TO SKIN AND RESPIRATORY TRACT.
Label Precautions:
Do not get in eyes.
Avoid breathing dust.
Keep container closed.
Use with adequate ventilation.
Wash thoroughly after handling.
Avoid contact with skin and clothing.
Label First Aid:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. In case of skin contact, wipe any excess material off skin and then immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. In all cases, get medical attention.
Product Use:
Laboratory Reagent.
Revision Information:
No Changes.
Disclaimer:
****
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THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT BAKER, INC. WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

****

Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b) (4)

[redacted]

Material Safety Data Sheet

Science Stuff, Inc.
1104 Newport Ave
Austin, TX 78753

Phone (512) 837-6020
Chemtrec 800-424-9300
24 Hour Emergency Assistance

Section 1 Identification

(b) (4)

[redacted]

Section 3 Hazard Identification (Also see section 11)

Harmful if swallowed. May cause irritation. Avoid breathing vapors, or dusts. Use with adequate ventilation. Avoid contact with eyes, skin, and clothes. Wash thoroughly after handling. Keep container closed.

Section 4 First Aid Measures

Harmful if swallowed. May cause irritation. Avoid breathing vapors, or dusts. Use with adequate ventilation. Avoid contact with eyes, skin, and clothes. Wash thoroughly after handling. Keep container closed.

Section 6 Accidental Release Measures

(b) (4)

[redacted]

Section 9 Physical and Chemical Properties

Melting Point:	237°C	Specific Gravity	1.735
Boiling Point:	Decomposes	Percent Volatile by Volume:	0
Vapor Pressure:	N/A	Evaporation Rate:	N/A
Vapor Density:	N/A	Evaporation Standard:	
Solubility in Water:	Soluble	Auto ignition Temperature:	Not applicable
Appearance and Odor:	White crystalline solid, acetic odor	Lower Flamm. Limit in Air:	Not applicable

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S1-28

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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[redacted]

(b) (4)

[redacted]

FIRST AID: SKIN: Wash exposed area with soap and water. If irritation persists, seek medical attention.

EYES: Wash eyes with plenty of water for at least 15 minutes, lifting lids occasionally. Seek Medical Aid. INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen

INGESTION: If swallowed, induce vomiting immediately after giving two glasses of water. Never give anything by mouth to an unconcious person.

Section 5 Fire Fighting Measures

Fire Extinguisher Type:	Water spray, Carbon dioxide, dry chemical, powder, foam.
Fire/Explosion Hazards:	None Known.
Fire Fighting Procedure:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and clothing.

Effects of overexposure, Acute and Chronic: Ingestions of large amounts can produce stomach cramps, stricture of esophagus, nausea, emesis. Contact with skin may have drying effect and cause irritation, redness and pain. May cause irritation and dryness to eyes. If inhaled, may cause irritation to lungs. Conditions aggravated/target organs: Persons with pre-existing eye, skin or respiratory conditions may be more susceptible.

DOT Classification: Not Regulated

DOT regulations may change from time to time. Please consult the most recent version of the relevant regulations.

Revision No:0 Date Entered: 9/1/2006 Approved by: WPF

The information contained herein is believed to be accurate and is offered in good faith for the user's consideration and investigation. No warranty is expressed or implied regarding the completeness or accuracy of this information, whether originating from Science Stuff, Inc. or from an alternate source. Users of this material should satisfy themselves by independent investigation of current scientific and medical information that this material may be safely handled.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Appendix 1-D: CI Reactive Blue 21 MSDS

(b) (4)

[redacted]

3. HAZARDS IDENTIFICATION

May cause sensitisation by skin contact

4. FIRST-AID MEASURES

Inhalation	Move to fresh air. Seek medical attention if you feel unwell or if exposure prolonged.
Skin contact	Remove contaminated clothing. Wash affected skin with soap and plenty of water.
Eye contact	Rinse immediately with plenty of water for at least 10 minutes.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Appendix 1-D: CI Reactive Blue 21 MSDS

(b) (4) [redacted]

Ingestion	Wash out mouth with water. Drink plenty of water.
Advice for the doctor	Symptomatic treatment
Further information	See section 16 of MSDS

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents	Waterspray, foam, powder, carbon dioxide.
Restrictions	No restrictions.
Fire/explosion hazard	None
Main combustion gas	Carbon, nitrogen and sulfur oxides
Personal protection	Self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal protection	Gloves, respiratory protection.
Environmental precautions	No special precautions
Spillage procedure	Damp down. Avoid dust. Scoop into marked containers for disposal as chemical waste. Flush residues away with water.

7. HANDLING AND STORAGE

Handling

Occupational hygiene	Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Storage

Fire precautions	No special measures required
Storage facilities	Store in a cool, dry area with adequate ventilation
Segregation	Keep away from alkali.
Storage conditions	Keep containers closed. Sensitive to heat over 40 °C.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits: None. Ensure adequate ventilation

Exposure Controls

Occupational exposure controls

General Personal Protection	Gloves, respiratory protection.
Hand protection	Chemical resistant protective gloves (EN 374). Recommended: permeation time >30 min. (level 2), material e.g. butyl or neopren. Observe glove manufacturers instructions.

9. PHYSICAL AND CHEMICAL PROPERTIES

General information

Appearance

Form	Powder
Colour	Blue

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Appendix 1-D: CI Reactive Blue 21 MSDS

(b) (4) [redacted]

Odour	None		

Important health safety and environmental information

pH	5 - 5.5		20 g/l
Boiling point	Not applicable		
Flash point	Not applicable		
Oxidising properties	None		
Solubility in water	80 g/l		at 30 °C
	80 g/l		90 °C

Other information

Melting point	> 250 °C		
Bulk density	657 kg/m3		
Thermal decomposition	230 °C		
Ignition temperature	480 °C	BAM	

10. STABILITY AND REACTIVITY

Conditions to avoid	None.
Materials to avoid	None
Hazardous decomposition products	None under normal storage conditions

11. TOXICOLOGICAL INFORMATION

Acute toxicity			
- LD50 oral	> 2000 mg/kg	Rat	
Primary Irritation			
(Skin)	Non-irritant	Rabbit	
(Eye)	Non-irritant	Rabbit	
Skin sensitisation	Sensitizing	Guinea Pig	OECD 406
Adverse effects in man	See 16 in MSDS		
Additional information			

12. ECOLOGICAL INFORMATION

Ecotoxicity

Bacterial toxicity			
	IC50	> 300 mg/l	3 hour
Fish toxicity	LC0	100 mg/l	48 hour Golden orfe
	LC50	> 100 mg/l	
Summary		Not toxic or harmful to aquatic organisms	

Persistance and degradability

Bioelimination	10-25%, DOC Analysis.	OECD 302B
Summary	Poorly eliminated by adsorption on effluent treatment sludge	
Behaviour in treatment plants	No inhibition. No nitrification inhibition known.	

Additional Ecology Data

Phosphorus content	0 %	
Organohalogen content	0 %	
Metal content	2.04 %	Copper as organo-metal complex

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b) (4)

[redacted]

least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.

Skin Contact:
Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: OPEN CUP: 79°C (174.2°F).

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO2).

Fire Hazards in Presence of Various Substances:
Flammable in presence of open flames and sparks, of heat.
Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available.
Slightly explosive in presence of open flames and sparks.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards:
Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b) (4)

on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. est. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, metals, acids, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Powdered solid. Amorphous solid powder.)

Odor: Odorless.

Taste: Not available.

Molecular Weight: (44.05)n g/mole

Color: Off-white. White. Colorless.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point:
Softens at about 200°C (392°F) with decomposition.
Decomposition @ 228 deg. C.

Critical Temperature: Not available.

Specific Gravity: 1.19-1.31(Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b) (4)
[redacted]

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility:
Soluble in cold water, hot water.
Insoluble in diethyl ether, acetone, petroleum solvents, aromatic hydrocarbons, esters.
Practically insoluble in animal and vegetable oils and chlorinated hydrocarbons.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Heat, ignition sources, flame, excess dust generation, incompatible materials.

Incompatibility with various substances: Reactive with oxidizing agents, metals, acids, alkalis.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Incompatible with oxidizing agents (perchlorates, nitrates, etc.), reactive metals (sodium, calcium, zinc. etc.), sodium or calcium hypochlorite, materials reactive with hydroxyl compounds. Reaction with peroxides may result in violent decomposition of peroxide possibly creating and explosion.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals:
Acute oral toxicity (LD50): 14700 mg/kg [Mouse].
Acute oral toxicity (LD50): > 20000 mg/kg [Rat].

Chronic Effects on Humans: CARCINOGENIC EFFECTS: 3 (Not classifiable for human.) by IARC.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: May cause cancer (tumorigenic) based on animal studies. No human data found at this time.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects:
Skin: May cause skin irritation.
Eyes: May cause eye irritation.
Ingestion: May cause gastrointestinal (digestive) tract irritation. May affect behavior/central nervous system (symptoms may include general depressed activity, altered sleep time, muscle weakness). May also affect blood and metabolism.
Inhalation: May cause respiratory tract irritation.
Chronic Potential Health Effects:
Inhalation or ingestion for prolonged period of time may affect blood and metabolism, and behavior.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b) (4)

[redacted]

May cause cancer (tumorigenic) based on animal studies. No human data found at this time.

Section 12: Ecological Information

Ecotoxicity: Ecotoxicity in water (LC50): 10000 mg/l 96 hours [Bluegill Sunfish]. >40000 mg/l 96 hours [Fatthead Minnow].

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Polyvinyl alcohol

Other Regulations: Not available.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):
This product is not classified according to the EU regulations.
Not applicable.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 2

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 0

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b) (4)

[redacted]

Flammability: 2

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves.
Lab coat.
Dust respirator. Be sure to use an approved/certified respirator or equivalent.
Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/10/2005 08:47 PM

Last Updated: 11/06/2008 12:00 PM

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall ScienceLab.com be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if ScienceLab.com has been advised of the possibility of such damages.

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Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b) (4)

[redacted]

For information in the US, call:	201-796-7100
Emergency Number US:	201-796-7100
CHEMTREC Phone Number, US:	800-424-9300

Section 2 - Composition, Information on Ingredients

(b) (4)

[redacted]

Hazard Symbols:	None listed
Risk Phrases:	None listed

Section 3 - Hazards Identification

EMERGENCY OVERVIEW

Caution! The toxicological properties of this material have not been fully investigated. May cause eye, skin, and respiratory tract irritation. Target Organs: None known.

Potential Health Effects

Eye:	May cause eye irritation.
Skin:	May cause skin irritation. May be harmful if absorbed through the skin.
Ingestion:	May cause irritation of the digestive tract. May be harmful if swallowed.
Inhalation:	May cause respiratory tract irritation. May be harmful if inhaled.
Chronic:	No information found.

Section 4 - First Aid Measures

Eyes:	Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. If irritation develops, get medical aid.
Skin:	Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical aid if irritation develops or persists.
Ingestion:	Do not induce vomiting. Get medical aid if irritation or symptoms occur.
Inhalation:	Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid if cough or other symptoms appear.
Notes to Physician:	

Section 5 - Fire Fighting Measures

General Information:	As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.
Extinguishing Media:	Use water spray, dry chemical, carbon dioxide, or chemical foam.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b) (4) [redacted]

Autoignition Temperature: Not available

Flash Point: > 150 deg C (> 302.00 deg F)

Explosion Limits: Lower: Not available

Explosion Limits: Upper: Not available

NFPA Rating: health: 1; flammability: 1; instability: 0;

Section 6 - Accidental Release Measures

General Information: Use proper personal protective equipment as indicated in Section 8.

Spills/Leaks: Absorb spill with inert material (e.g. vermiculite, sand or earth), then place in suitable container. Provide ventilation. Do not let this chemical enter the environment.

Section 7 - Handling and Storage

Handling: Use with adequate ventilation. Avoid contact with eyes, skin, and clothing. Avoid ingestion and inhalation.

Storage: Store in a cool, dry place. Store in a tightly closed container. Store at around 20°C.

(b) (4) [redacted]

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.

Exposure Limits

Personal Protective Equipment

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin: Wear appropriate protective gloves to prevent skin exposure.

Clothing: Wear appropriate protective clothing to prevent skin exposure.

Respirators: A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149 must be followed whenever workplace conditions warrant respirator use.

Section 9 - Physical and Chemical Properties

Physical State: Viscous liquid

Color: clear yellow to amber

Odor: Not available

pH: 6 (10% aq.sol.)

Vapor Pressure: Not available

Vapor Density: Not available

Evaporation Rate: Not available

Viscosity: 400 mPa @ 50 deg C

Boiling Point: > 100 deg C @ 760 mmHg (> 212.00°F)

Freezing/Melting Point: Not available

Decomposition Temperature: Not available

Solubility in water: 100 g/L

Specific Gravity/Density: 1.100

Molecular Formula:

Molecular Weight:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b) (4) [redacted]

Section 10 - Stability and Reactivity

Chemical Stability:	Stable under normal temperatures and pressures.
Conditions to Avoid:	Incompatible materials, excess heat.
Incompatibilities with Other Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Carbon monoxide, carbon dioxide.
Hazardous Polymerization	Has not been reported.

Section 11 - Toxicological Information

(b) (4) [redacted]

Teratogenicity:	Teratogenic effects have occurred in experimental animals.
Reproductive:	Adverse reproductive effects have occurred in experimental animals.
Neurotoxicity:	No information found
Mutagenicity:	No information found
Other:	See actual entry in RTECS for complete information.

Section 12 - Ecological Information

Other: Do not empty into drains.

Section 13 - Disposal Considerations

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification. RCRA P-Series: None listed. RCRA U-Series: None listed.

Section 14 - Transport Information

US DOT
Shipping Name: Not regulated.
Hazard Class:
UN Number:
Packing Group:
Canada TDG
Shipping Name: Not regulated as a hazardous material
Hazard Class:
UN Number:
Packing Group:

Section 15 - Regulatory Information

US Federal

TSCA

(b) (4) [redacted]

Health & Safety Reporting List	None of the chemicals are on the Health & Safety Reporting List.
Chemical Test Rules	None of the chemicals in this product are under a Chemical Test Rule.
Section 12b	None of the chemicals are listed under TSCA Section 12b.
TSCA Significant New Use Rule	None of the chemicals in this material have a SNUR under TSCA.
CERCLA Hazardous Substances and	None of the chemicals in this material have an RQ.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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(b) (4) [redacted]

corresponding RQs	
SARA Section 302 Extremely Hazardous Substances	None of the chemicals in this product have a TPQ.
Section 313	No chemicals are reportable under Section 313.
Clean Air Act:	This material does not contain any hazardous air pollutants. This material does not contain any Class 1 Ozone depletors. This material does not contain any Class 2 Ozone depletors.
Clean Water Act:	None of the chemicals in this product are listed as Hazardous Substances under the CWA. None of the chemicals in this product are listed as Priority Pollutants under the CWA. None of the chemicals in this product are listed as Toxic Pollutants under the CWA.
OSHA:	
STATE	(b) (4) [redacted]
California Prop 65	
California No Significant Risk Level:	None of the chemicals in this product are listed.

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols:Not available

Risk Phrases:

Safety Phrases:

S 24/25 Avoid contact with skin and eyes.

WGK (Water Danger/Protection)

(b) (4) [redacted]

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by those regulations.

CAS# 9005-64-5 is not listed on Canada's Ingredient Disclosure List.

Section 16 - Other Information

MSDS Creation Date: 12/11/1997

Revision #5 Date 11/29/2007

Revisions were made in Sections: 3, 4, 5, 6, 7, 8, 9, 10, 11, 1

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantibility or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall the company be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential, or exemplary damages howsoever arising, even if the company has been advised of the possibility of such damages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Supplementary Response to FDA Request
Stage II – May 25, 2010.

Filligent (HK) Limited submitted a 510(k) premarket notification for the BioFriend™ BioMask™ Surgical Facemask Models: Universal BF-200-2001 and Premium BF-200-3013 (reference K101128) on Thursday April 22, 2010 (the ***510(k) Premarket Notification***). On Wednesday, April 28, 2010 an email request from Dr Sheila Murphey, Medical Officer, Infection Control Devices Branch, was received requesting Filligent to provide further information (the ***FDA Request***). Our supplementary response has been in two stages. The first stage was submitted on Tuesday, May 4, 2010 and addressed questions 4 to 10 of the FDA Request (a copy of which was attached to the cover letter for easy reference).

This document comprises the second stage to our supplementary response, which addresses the remaining queries of the FDA Request, namely questions 1 to 3 inclusive, which are set forth below:

(b) (4)

[redacted]

2. The acceptance criteria for the pH of the outer layer of your devices

3. The pH of the second layer of your devices when the aerosols contacting the outer layer are "drawn into" the second layer

. . . . . .

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

1.1.1 Outline of Methodology

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Figure 1.0 Experimental Design

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

The MEC for zinc (as zinc acetate) against Human Influenza A (H1N1) A/Brisbane/59/2007, defined as the concentration required to reduce the original inoculum by 4 $\log_{10}$ in 5 minutes was determined to be between 0.1% to 0.25% w/v Zn^{2+}.

Table 1.4 Assessment of the MEC of Citric Acid against Influenza A (H1N1) A/Brisbane/59/2007

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

concentration required to reduce the original inoculum by 4 $\log_{10}$ in 5 minutes was determined to be between 0.01% to 0.1% w/v (0.5mM – 5mM).

Citric acid, used as the hydrophilic plasticizing agent for the polyvinyl coating, is an organic carboxylic acid and lowers the pH of its environment (pKa = 3.13). Low pH can cause denaturation (structural changes) of proteins. Many enveloped viruses such as influenza have been observed to be inactivated at pH 5-6 or below, a consequence of structural changes in proteins of the lipid envelop (Refer to Section 11.4.1 – Mode of Action, pages 11-10 of the 510(k) Premarket Notification). A 0.1% w/v final solution has a pH of 2.79, and a 0.01% w/v final solution has a pH of 3.45% (Table 1.5).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Table 1.5 pH of the Citric Acid Test Solutions assessed in the MEC Determination

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

1.1.3 Test Reports

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Question **2. The acceptance criteria for the pH of the outer layer of your devices**

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

The pH of the outer polypropylene layer coated with hydrophilic plastic was assessed by extracting the chemicals which influence pH from the material layer in water, the pH of which is then measured. The

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Question 3. The pH of the second layer of your devices when the aerosols contacting the outer layer are "drawn into" the second layer

Both models of the BioFriend™ BioMask™ surgical facemask are identical in all respects other than shape. The second layer of the BioFriend™ BioMask™ surgical facemask was excised from either 1) a

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Figure 3.1 Time Series Photographs of Droplet Absorption of Facemasks With or Without Hydrophilic Plastic Coated Polypropylene

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

Records processed under FOIA Request #2015-5619; Released by CDRH on 06-06-2016.

Appendix 1

(b)(4) Deficiencies and Responses to Deficiencies

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

(b)(4) Deficiencies and Responses to Deficiencies

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