Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

TAB 5

510(K) SUMMARY

JUN 14 2010

Date of Submission	11/9/09
Official Contact / Address of Manufacturing facility	Matthew Young Manager, Quality Assurance and Regulatory Affairs Children's Medical Ventures 191 Wyngate Drive Monroeville, PA 15146 Phone: 724-387-4012 Fax: 412-380-8850 Email: matthew.young@philips.com
Proprietary Name	Oral/Enteral Syringes
Common/Usual Name	Gastrointestinal tubes and accessories
Classification Reference	21 CFR 876.5980
Classification	Class II
Appropriate Classification Panel	Gastroenterology / Urology
Product Code	FPD
Predicate Devices	Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944) Respironics, Inc. Enteral Only Extension Set (K082654)

Intended Use/Indications for Use

The Oral/Enteral Syringes is intended for the delivery of liquid medication, formula, and breast milk.

Patient Population/Environment of Use

The patient population is neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral/Enteral Only Syringes is disposable and for single patient use only.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Substantial Equivalence

This traditional 510(k) submittal demonstrates that the Oral/Enteral Syringes are substantially equivalent to the Respironics, Inc. Enteral Only Extension Set (K082654) and the Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944).

Design verification tests were performed on the Oral/Enteral Syringes as a result of the risk analysis and product requirements. The following tests were conducted:

- Volume Measurement Accuracy Testing
- Enteral Feeding Extension Set Interface Testing
- Size and Material Inspection
- Biocompatibility Testing
- Sterility Testing
- Reliability Inspection
- Labeling Inspection
- Environmental Operating Testing
- Storage Testing
- ISTA Testing

Testing Results demonstrated that the Oral/Enteral Syringes meet the required acceptance criteria. Children's Medical Ventures has determined that the Oral/Enteral Syringes are substantially equivalent to the predicate devices.

Device Description

The Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk. The syringes incorporate safety connectors that mate with the Respironics Enteral Only Extension Set, but will not mate with Luer lock or Luer slip fittings. The safety connectors prevent inadvertent connection of the enteral system to an IV system or an IV system to the enteral system. The Oral/Enteral Syringe barrels, plungers and end caps are comprised of Polypropylene, and the pistons are comprised of Silicone.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6C
Silver Spring, MD 20993-0002

Philips Children's Medical Ventures
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUN 14 2010

Re: K100099
Trade/Device Name: Oral/Enteral Syringes
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: FPD
Dated: June 3, 2010
Received: June 4, 2010

Dear Mr. Job:

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.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

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,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological 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 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Indications for Use

510(k) Number (if known): K100099

Device Name: Oral/Enteral Syringes

Intended Use/Indications for Use:

Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk.

Patient Population/Environment of Use:

The patient population is neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral/Enteral Syringes are disposable and for single patient use only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100099

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Philips Children's Medical Ventures
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUN 14 2010

Re: K100099
Trade/Device Name: Oral/Enteral Syringes
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
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Product Code: FPD
Dated: June 3, 2010
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Dear Mr. Job:

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.

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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

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00002

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological 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 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00003

Indications for Use

510(k) Number (if known): K100079

Device Name: Oral/Enteral Syringes

Intended Use/Indications for Use:

Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk.

Patient Population/Environment of Use:

The patient population is neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral/Enteral Syringes are disposable and for single patient use only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100099

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

Records processed under FOIA Request # 2016-1066; 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

May 28, 2010

PHILIPS CHILDREN'S MEDICAL VENTURES
c/o REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET, NW
BUFFALO, MINNESOTA 55313
UNITED STATES
ATTN: MARK JOB

510k Number: K100099
Product: ORAL/ENTERAL SYRINGES

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 301-796-8118

Records processed under FOIA Request #2016-1066; Released by CDRH on 06-06-2016

DJA 00020

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

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00088

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

March 03, 2010

PHILIPS CHILDREN'S MEDICAL VENTURES
c/o REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET, NW
BUFFALO, MINNESOTA 55313
UNITED STATES
ATTN: MARK JOB

510k Number: K100099
Product: ORAL/ENTERAL SYRINGE

Extended Until: 06/03/2010

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 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Date: February 26, 2010

FDA CDRH DMC
MAR - 2 2010
Received

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

RE: Premarket Notification 510(k):

K100099
PHILIPS CHILDREN'S MEDICAL VENTURES
ORAL/ENTERAL SYRINGES

To Whom It May Concern:

This letter is a request for a 90 day extension in order to complete the preparation of the response to the email from Jeffery Cooper dated January 22, 2010.

If you should have any questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

K46

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00090

Date: February 26, 2010

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

RE: Premarket Notification 510(k):

K100099
PHILIPS CHILDREN'S MEDICAL VENTURES
ORAL/ENTERAL SYRINGES

To Whom It May Concern:

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Sincerely,

Mark Job
Responsible Third Party Official

K44

DJA 00091

Records processed under FOIA Request # 2016-1066; 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 26, 2010

PHILIPS CHILDREN'S MEDICAL VENTURES
c/o REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET, NW
BUFFALO, MINNESOTA 55313
UNITED STATES
ATTN: MARK JOB

510k Number: K100099
Product: ORAL/ENTERAL SYRINGES

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 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00092

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

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

DJA 00101

Records processed under FOIA Request # 2016-1066; 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 14, 2010

PHILIPS CHILDREN'S MEDICAL VENTURES
c/o REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET, NW
BUFFALO, MINNESOTA 55313
UNITED STATES
ATTN: MARK JOB

510k Number: K100099

Received: 1/13/2010

Product: ORAL/ENTERAL SYRINGES

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

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00102

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 301-796-8118

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DJA 00103

K100099

Date: January 12, 2010

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

FDA CDRH DMC

JAN 13 2010

Received

RE: Premarket Notification

To Whom It May Concern:

Enclosed in duplicate is the following information:

A. Purpose of Submission: New Device

B. Name and Address of the Third Party:

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

C. Name and Address of the Manufacturer:

Philips Children's Medical Ventures

191 Wyngate Drive

Monroeville, PA 15146

K15

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

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DJA 00104

D. Device Name

Trade or Proprietary Name: Oral / Enteral Syringes

Classification Name: Gastrointestinal Tube and Accessories

Regulation Number: 21 CFR 876.5980

Recommendation: Substantially Equivalent

Date Submission was received by Regulatory Technology Services LLC: November 10, 2009

We have enclosed the following materials:

E. Authorization Letter from the applicant (MAL-F-0006).
F. Complete 510(k) application submitted by the applicant.
G. Documented review of the 510(k) application (RPP-F-0012, RPP-F-14 and all correspondence and documents related to the review).
H. Conflict of Interest Certification (COI-F-0018)
I. Certification (RPP-F-0020)

If you should have any questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420 or mark@markjob.com. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

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

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DJA 001105

Submission Certification

1. I certify that Regulatory Technology Services LLC continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by the FDA;

2. In addition, I state that Regulatory Technology Services LLC believes that statements made in the review are true and accurate to the best knowledge of Regulatory Technology Services LLC;

3. Regulatory Technology Services LLC's review is based on the 510(k) that is attached with the review; and

4. Regulatory Technology Services LLC understands that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 33(q).

Mark Job

Print Name of Accredited Person Responsible Official

Signature

Date: January 12, 2010

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00106

Conflict of Interest
Declaration and Certification
For the review of the 510(k) submission from

Applicant: Philips Children's Medical Ventures

Device Name or Model Name: Oral / Enteral Syringes

Initials

- I have read and understand Regulatory Technology Services LLC's Conflict of interest and Confidentiality Procedure (COI-S-0023), regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.
- I have not been employed within the last two years by the firm who submitted the 510(k) for evaluation.
- I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).
- I have not performed testing in connection with this specific device 510(k).
- I understand that the Accredited Persons (AP) Program requires that the Accredited Person or any of its personnel involved in 510(k) reviews, which includes those who have authority over the review process, have no ownership or other financial interest in a device manufacturer or distributor that presents the appearance of a conflict of interest.
- I do not participate in the design, manufacture or distribution of any medical device.
- I do not provide consultative services to any device manufacturer or distributor regarding specific devices.

Signed: _____

Printed Name: Mark Job

Date: November 10, 2009

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

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DJA 00107

Third Party Review
Reviewer Memorandum

Third Party Organization: Regulatory Technology Services LLC

Primary Reviewer: Mark Job

Signature: Date: January 12, 2010

Print Name: Mark Job Title: Reviewer

Responsible Third Party Official

Signature: (b)(6) Date: January 12, 2010

Print Name: Title: Program Supervisor

510(k) Applicant's Name: **Philips Children's Medical Ventures**

Device Name: **Oral/Enteral Syringes**

Contact Person: Lisa Casavant

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

I. Purpose and Submission Summary:

The 510(k) holder (**Children's Medical Ventures**) would like to introduce **Oral/Enteral Syringes** into interstate commerce. During the review deficiencies were found which required additional information from the sponsor. The sponsor provided a response to all concerned items and all questions are resolved. This submission is very similar to the predicate devices. The submission includes performance testing protocols, purpose, pass / fail criteria, and a summary of the results.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription) Page Number: **TAB 4**	X		
Truthful and Accuracy Statement Page Number: **TAB 6**	X		
510(k) Summary Page Number: **TAB 5**	X		
Standards Form (FDA Form 3654) Page Number: **TAB 9**	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

The Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk. The syringes incorporate safety connectors that mate with the Respironics Enteral Only Extension Set, but will not mate with Luer lock or Luer slip fittings. The safety connectors prevent inadvertent connection of the enteral system to an IV system or an IV system to the enteral system. The

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

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submission states the Oral/Enteral Syringes are intended to be used in the hospital or home environment, by trained caregivers only.

Material Description

The Oral/Enteral Syringes are comprised of four parts; the barrel, plunger, the piston, and an end cap. The material used to manufacture each part is found in the table below.

Materials used to manufacture the Oral/Enteral Syringes

Part	Material
Barrel	Polypropylene (b)(4)
Plunger	Polypropylene (b)(4)
Piston stopper (attaches to end of plunger to create seal)	(b)(4) Silicone (b)(4)
End Cap (attached to output port of barrel)	(b)(4)

All materials have been evaluated in accordance with ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. The submission includes the details of the testing and the test results.

The device description is similar to the predicate devices and does not raise any questions related to safety and effectiveness.

IV. Indications for Use

Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk.

Patient Population/Environment of Use:

The patient population is neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral/Enteral Syringes are disposable and for single patient use only.

The indications for use form is included in the submission in TAB 4. The device is for prescription use. The intended use is the same as the combination of the predicate devices.

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

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V. Predicate Device Comparison

The submission provides a comparison between the new device the Children's Medical Ventures Oral/Enteral Syringes and the predicate devices the Vygon Nutrisafe 2 System Transparent Syringes cleared under K060944 and the Respironics Enteral Extension Set cleared under K082654. The following is a comparison table which includes a comparison of the indications for use and the device specifications.

	Predicate Device: Respironics Inc. Enteral Only Extension Set (K082654)	**Predicate Device:** Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944)	**Proposed Device:** ChMV Oral/Enteral Syringes
Intended use	The Enteral Only Extension Set is intended for use as an extension set for nasogastric/ oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors which reduce the risk of accidental connection of an I.V. system to the enteral system, or the enteral system to an I.V. system.	For nasogastric/oralgastric enteral feeding.	Oral/Enteral Syringe is Intended for delivery of liquid medication, formula, and breast milk.
Environment of Use	Hospital/institutional environment	Hospital, home, or environments where placement of a feeding tube is required	Hospital and home environment by trained caregivers only.
Patient Population	Pediatric and adult use	Neonates and Infants	Neonates and Infants
Product Code (Regulatory Description)	KNT	FPD	FPD
Patient Usage Type	Single use	Single use	Single use
Device Usage Type	Disposable	Disposable	Disposable
Design	Connects to enteral syringes and enteral extension sets	Connects to enteral feeding tubes or enteral extension sets	Connects to enteral feeding tubes or enteral extension sets
Non-IV Compatible Connector	Yes	Yes	Yes
Material	(b)(4)	Unknown	Barrel & Plunger: Polypropylene (b)(4) Piston: (b)(4) Silicone (b)(4) End Cap: (b)(4)
Sizes	60" (152 cm) and 36" (91 cm)	1, 2, 5, 10, 20, and 60 ml	1, 3, 5, 10, 20, 30, and 60 ml
Sterility Condition	Sterile	Sterile	Sterile
Packaging Material	(b)(4) pouch	unknown	(b)(4) (b)(4)

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

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DJA 00111

The table above demonstrates the new device has the same intended use, similar physical properties, the same performance characteristics, and similar materials as the predicate devices.

This comparison does not raise new questions of safety and effectiveness.

VI. Labeling

The labeling includes all the appropriate cautions and warnings to the user. The labeling is contained within the TAB 13 of the submission. The labeling includes all instructions and warnings related to the use of the subject device. The labeling includes samples of each version (size) included in this submission. The labeling is similar to the labeling of the predicate device which was not provided but was extracted from the website and included as part of this document with the clearance letter from the FDA website. No new claims are made which would raise questions of safety and effectiveness.

VII. Sterilization/Shelf Life/Reuse

The sterilization information is included in section 14 of the submission. The sterilization validation is declared to be validated according to the (b)(4): (b)(4) of the standard. This method will be sufficient to ensure product is sterile. The devices will be sterilized using (b)(4). The validation of the sterilization process will demonstrate the product has a sterility assurance level (SAL) of 10(b)(4). This level of is adequate for device to be considered sterile. The sterilization information included in TAB 14 includes information related to the evaluation of the residuals (page 1). All information presented indicates the new device meets specifications. The sterilization method use for the new device though not clearly stated in the submission is the same as the predicate devices. The package information is stated to be identical to the device (a syringe) cleared under K042500. No new questions of safety and effectiveness are raised.

VIII. Biocompatibility

The device has been tested to demonstrate conformance to the appropriate parts of ISO 10993 to ensure compatibility to the materials. The following table provides a reference between each component and material and the type of contact to the patient and / or fluid.

Oral/Enteral Syringe Component	Type of Patient Contact	Contact with feeding solution?	Material
Barrel	Indirect	Yes	Polypropylene (b)(4)
Plunger	Indirect	No	Polypropylene (b)(4)
Piston (attaches to end of plunger to	Indirect	Yes	(b)(4) Silicone (b)(4)

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

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create seal)			
Lubricant	Indirect	Yes	(b)(4)
End Cap (attached to output port of barrel)	Indirect	No	(b)(4)

The following table presents the results of the tests performed for each component of the device.

Component	Material	Testing or Analysis performed
Barrel	The barrel is polypropylene (b)(4). Color: *1 ml-* Orange (b)(4) *5 ml–60 ml-* Transparency	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
Piston	The piston is (b)(4) Silicone (b)(4) (b) Color: Black	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
Plunger	The plunger is polypropylene (b)(4) Color: *1 ml-* White *5 ml-60 ml-* Orange (b)(4)	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
Lubricant	The syringe lubricant is (b)(4) (b)(4)	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
End Cap	The end cap is (b)(4) Color: Orange (b)(4)	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}

The table above provides a summary of the actual test reports provided in the submission and the additional information dated January 7, 2010. The test reports demonstrate for short duration (<24 hours) contact of intact mucosal membrane the tests are appropriate and meet the requirement for this type of contact in accordance with Blue book Memo G95-1. No new questions related to the safety are raised.

IX. Software

This device does not employ software.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

This is not electrically powered.

XI. Performance Testing – Bench

The submission includes bench testing performed to verify the design

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

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DJA 00113

performance of the Oral/Enteral Syringes. The following table extracted from the submission provides a summary of the tests performed.

PRD (reference 1) Requirement	Verification Test Procedure (reference 4)	Test Result
(b)(4)		

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

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DJA 00114

PRD (reference 1) Requirement	Verification Test Procedure (reference 4)	Test Result
(b)(4)		

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

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PRD (reference 1) Requirement	Verification Test Procedure (reference 4)	Test Result
(b)(4)		

The submission states the test results which are indicated as "not performed" are related to the sterilization process and will be completed before the device is placed on the market. The additional information dated January 7, 2010 includes additional information which states this device is manufactured using similar manufacturing process and similar design properties and the sterilization process and packaging is identical to the device cleared previously cleared under K042500.

The testing results indicate the Oral/Enteral Syringes meets the design requirements. The performance testing included in the submission also includes side by side testing with the predicate device. The Performance Test data is presented in TAB 18. Scientifically the test results demonstrate the safety and effectiveness of the device. No new concerns related to performance of the new device are raised.

XII. Performance Testing – Animal

This submission does not include animal clinical testing or data.

XIII. Performance Testing – Clinical

This submission does not include human clinical testing or data

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

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XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		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?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	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?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

Note: Document the decision path by marking the arrows followed on the FDA flowchart.

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:

   The submission includes the descriptive characteristics but the performance testing is needed to solidify the discussion of substantial equivalence through performance testing which demonstrates in side by side comparisons between the new device and the predicate device the new device employs similar.

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 301-796-8118

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DJA 00117

7. Explain why existing scientific methods cannot be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

As the reviewer of this submission I have reviewed the instructions for use, the submitter's description of the device and compared this information against the information concerning the predicate devices that was provided by the submitter. The specifications for the predicate device and the new device have been compared. They are nearly identical. The comparison differences described in the comparison table are similar between the devices. The submission states the patient contact materials are similar to the predicate devices and the test results have been included in the submission in TAB 18. The sterilization and packaging are not indicated as being different than the predicates but they are presented and meet the prescribed FDA requirements. The submission includes performance testing which demonstrating in side by side comparisons between the new device and the predicate device the new device employs similar performance characteristics. The labeling included in the submission was reviewed. There are no new questions of safety and effectiveness raised during this review.

Based upon the above summary, a substantially equivalent decision is recommended.

XV. Deficiencies

All deficiencies presented to the sponsor are included in the documentation of the review and are included in this submission. The sponsor has addressed all deficiencies.

XVI. Contact History

All correspondence is included in the submission.

XVII. Recommendation

Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: FPD

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

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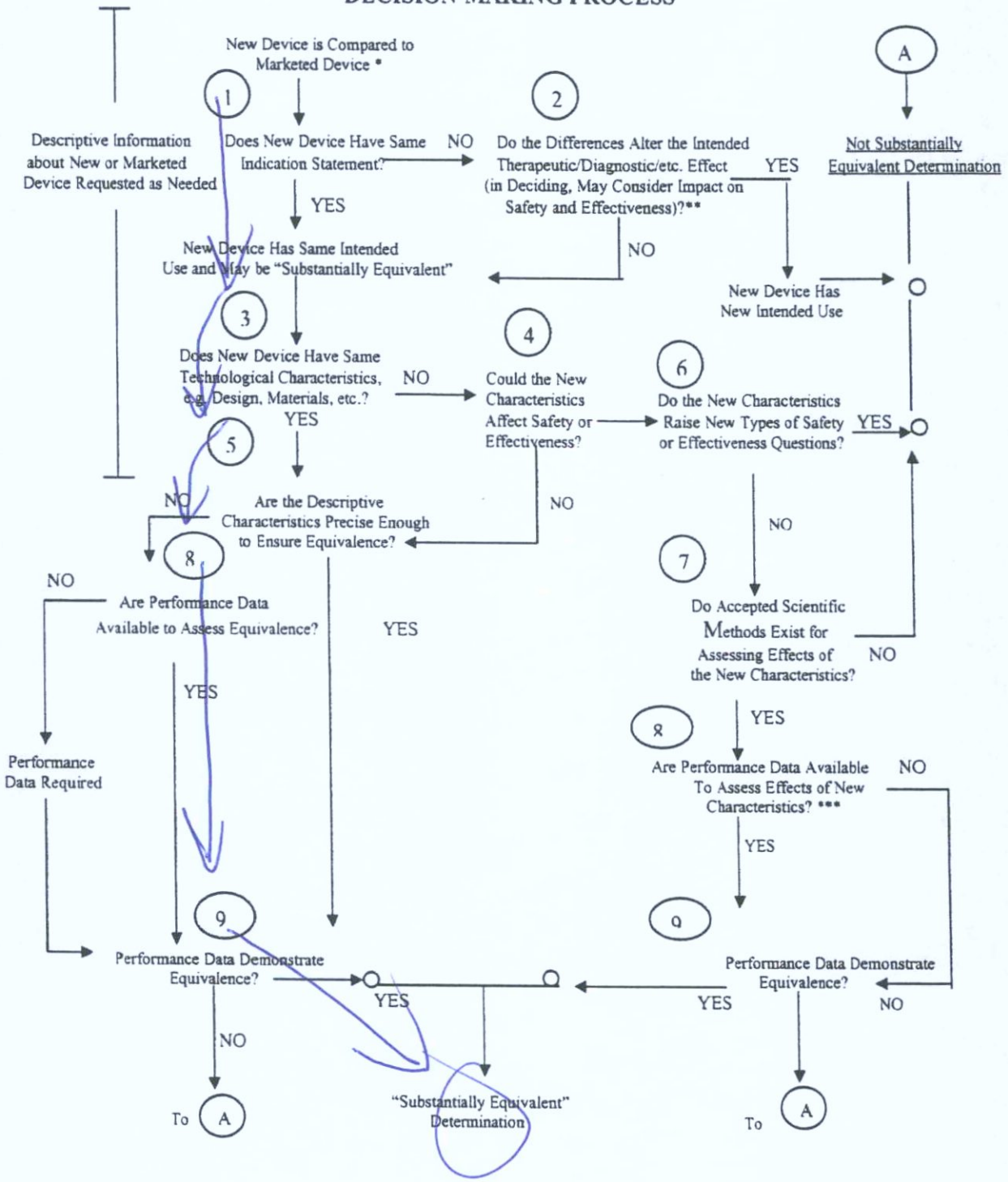
DJA 00118

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 301-796-8118

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DJA 00119

January 7, 2010

Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

ATTN: Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

RE: Response to RAI, 510(k) Notification, Children's Medical Ventures' Oral/Enteral Syringes

Dear Mark:

Children's Medical Ventures (ChMV) hereby submits this response to your request for additional information. If you require additional information, please do not hesitate to contact me by phone or E-mail.

Sincerely,

Lisa Casavant

Primary Contact:
Name: Lisa Casavant
Title: Regulatory Affairs Consultant
Phone: 724-244-2624
Fax: 412-380-8850
Email: Lisa.Casavant@philips.com

Secondary Contact:
Name: Matthew Young
Title: Manager, Quality Assurance and Regulatory Affairs
Phone: 724-387-4012
Fax: 412-380-8850
Phone: Matthew.Young@phillips.com

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

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DJA 00120

QUESTION #1: (b)(4) [redacted] ?

(b)(4) Deficiencies

[redacted]

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

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DJA 00121

RESPIRONICS

Philips Children's Medical Ventures

Oral/Enteral Syringe Biocompatibility Assessment Report

Version (b)(4)

ER (b)(4)

Prepared for:

Philips Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

Prepared by:

Lisa Casavant

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

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DJA 00122

(b)(4)

Revision History

DOCUMENT REVISION RECORD				
Version	Date	Pages	Description	Contributors
(b)(4)	10/09/09	All	Original release of document.	L. Casavant
	1/7/10	All	Addition of biocompatibility test reports for testing conducted (b) (b) sterilization.	L. Casavant
Notes:				

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

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DJA 00123

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1.0 INTRODUCTION
- 1.1 Purpose
- 1.2 Scope
- 1.3 References

2.0 ASSESSMENT METHODOLOGY

3.0 CATEGORIZATION AND TEST DETERMINATION

4.0 BIOCOMPATIBILITY TEST RESULTS

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00124

(b)(4) Biocompatibility Assessment Report

[redacted]

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00125

(b)(4) Biocompability Assessment Report

[redacted]

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

(b)(4) Third Party Testing

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Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00189

Date: November 20, 2009

Lisa Casavant
Philips Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

Re: Oral / Enteral Syringes

Dear Ms. Casavant,

We have completed the substantive review according to the 510(k) checklist, a FDA general guidance document for preparing a 510(k), and a discussion with the FDA (Gastroenterology Devices branch) concerning the (b)(4) (b)(4) (b)(4) (b)(4) These deficiencies are described in the attached Record of Deficiencies from the Substantive Review. Please respond to these items in writing. Your submission is currently on hold until we receive the additional information.

If you have any questions, please do not hesitate to contact me. You may reach me at 763 682 4139.

Sincerely,

Mark Job
Reviewer

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

DJA 00190

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Record of Deficiencies From Substantive Review

Device Name or Model Name: EndoVive Low Profile Replacement Gastrostomy Tube

Date: November 20, 2009

Please provide the following items as required according to 510(k) checklist, a FDA general guidance document for preparing a 510(k) and a discussion with the FDA (Gastroenterology Devices branch) concerning the review of a device included in the expansion pilot

(b)(4) [redacted]

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00191

Date: November 10, 2009

Lisa Casavant
Philips Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

Re: Oral / Enteral Syringes

Dear Ms. Casavant,

This letter is to acknowledge that on November 10, 2009, Regulatory Technology Services LLC received the 510(k) dated November 9, 2009 for the Oral / Enteral Syringes.

We have completed the administrative review according to the 510(k) checklist, a FDA general guidance document for preparing a 510(k), and a discussion with the FDA (Gastroenterology Devices branch) concerning the (b)(4) [redacted] We found all items present. We have begun the substantive review of your submission. We will keep you informed as the review progresses

If you have any questions, please do not hesitate to contact me. You may reach me at 763 682 4139.

Sincerely,

Mark Job
Reviewer

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

DJA 00192

Records processed under FOIA Request # 2016-1066 Released by CDRH on 06-06-2016

Summary of Discussion with Branch Chief

Date:	November 10, 2009	FDA Branch:	Gastroenterology
Reviewer:	Mark Job	Branch Chief:	
Review	Oral / Enteral Syringes		

NOTE: Due to the knowledge of this type of device by this reviewer no contact was made with the Gastroenterology branch. The content from the previous submissions was used as a guide during this review. Contact is deemed as not necessary.

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

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DJA 00193

Part Acceptance / Non-acceptance

1. Accredited Person:

Name: Regulatory Technology Services LLC

Address 1394 25th Street NW

Buffalo, MN 55313

Contact: Mark Job

Telephone: 763 682 4139 Fax: 763 682 4420

2. Foreign Accredited Person, Specify a Domestic Correspondent:

Name: _____

Address _____

_____

Contact: _____

Telephone: _____ Fax: _____

3. 510(k) Owner (Applicant, Manufacturer, other persons preparing 510(k))

Name: Philips Children's Medical Ventures

Address 191 Wyngate Drive

Monroeville, PA 15146

Contact: Lisa Casavant

Telephone: 724 244 2624 Fax: 412 380 8850

STOP!

Before completing items 4 to 9 below, complete pages 3 – 6 of this document.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00194

4. Device Name:

Trade or Proprietary Name: Oral / Enteral Syringes

Classification Name: Tubes, Gastrointestetinal (and accessories)

5. CFR Classification Citation: 21 CFR 876.5980
(see 21 CFR 862 through 892)

6. Classification Panel: Gastroenterology

7. Based on my completion of this document, I recommend that this 510(k):

☒ Be accepted for substantive review and I have notified the 510(k) owner using RPP-F-0016.

☐ Not be accepted for substantive review and I have listed the deficiencies on RPP-F-0016.

8. Primary Reviewer

Signature

November 10, 2009
Date

Mark Job
Print Name

9. Supervisor

(b)(6) [redacted]
Print Name

1/12/2010
Date

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Checklist Questions:	YES	NO	Instructions
1. a). Is the device one that FDA has determined as being acceptable for third party review?	☒	☐	If NO, telephone DSMA for instructions. --STOP REVIEW--
1 b). Have you confirmed that the manufacturer has not engaged in forum shopping?	☒	☐	If NO, telephone DSMA for instructions. --STOP REVIEW--
2. Is the device trade or proprietary name included?	☒	☐	If NO, note deficiency on RPP-F-0013.
3. Is the device common or usual name included?	☒	☐	If NO, note deficiency on RPP-F-0013.
4. Is the device classification name, class of the device, and regulation number (21 CFR 876.5980) included?	☒	☐	If NO, note deficiency on RPP-F-0013.
5. Is the classification panel included?	☒	☐	If NO, note deficiency on RPP-F-0013.
6. Has the applicant complied with Section 514 of the Act? (Section 514 relates to performance standards for class II devices. At this time, there are no 514 standards. Therefore, your answer should be yes.)	☒	☐	If NO, note deficiency on RPP-F-0013.
7. Does the submission include proposed labels, labeling, and advertisements (if available) that describe the device, its intended use, and directions for use (ODE Guidance Memorandum #G91-1)?	☒	☐	If NO, note deficiency on RPP-F-0013.
8. Does the submission contain the "Indications for Use" form?	☒	☐	If YES, indicate page number TAB. 4 If NO, note deficiency on RPP-F-0013.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00196

Checklist Questions:	YES	NO	Instructions
9. Does the submission contain an acceptable 510(k) Summary of Safety and Effectiveness (per 21 CFR 807.92) OR an acceptable 510(k) Statement (per 21 CFR 807.93) that safety and effectiveness information will be made available to any person upon request?	☒	☐	If YES, indicate page number TAB 5 If NO, note deficiency on RPP-F-0013.
10. Does the submission contain photographs of the device if applicable?	☒	☐	If NO, note deficiency on RPP-F-0013.
11. Does the submission contain drawings for the device with dimensions and tolerances if applicable?	☐ N/A	☐	If NO, note deficiency on RPP-F-0013.
12. Does the submission identify the device to which equivalence is claimed?	☒	☐	
13. If the answer to question 12 is YES, did the applicant identify:			
a. Predicate device (referred to as marketed device)?	☐	☒	
b. Legally marketed device (referred to as marketed device)?	☒	☐	Note deficiency on RPP-F-0013.
Note: A predicate device is a device that was legally in commercial distribution in the U.S. on or before May 28, 1976 (referred to as a pre-amendments device) or a device that was marketed after May 28, 1976 (referred to as a post amendments device) that was reclassified from class III to class I or II. A marketed device can be a predicate device but is most often a device that FDA has determined is SE to another marketed device (21 CFR 807.92(a)3). IT IS YOUR RESPONSIBILITY TO MAKE SURE THAT THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE IDENTIFIED IS LEGITIMATE. If it is not, the review must STOP. Telephone DSMA for assistance.			List all 510(k) control numbers: K082654 K060944

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Checklist Questions:	YES	NO	Instructions
14. Does the submission contain information about the marketed device(s) identified in questions 12 and 13 above to which equivalence is claimed, including labeling and a description of the device?	☒	☐	If NO, note deficiency on RPP-F-0013.
15. Does the submission contain a statement/comparison of similarities and/or differences between the new device and the marketed device? (The new device that is the subject of this 510(k) can be either a new device or a modification to the existing device.)	☒	☐	If NO, note deficiency on RPP-F-0013.
16. Does the submission contain the Truthful and Accurate Statement (per 21 CFR 807.87(j))?	☒	☐	If YES, indicate page number TAB 6 If NO, note deficiency on RPP-F-0013.
17. Does the submission contain the submitter's name, address, contact person, telephone number, and fax number?	☒	☐	If NO, note deficiency on RPP-F-0013.
18. If there is a representative or consultant, does the submission contain their name, address, contact person, telephone number, and fax number?	☐ N/A	☐	If NO, note deficiency on RPP-F-0013.
19. Does the submission contain a table of contents with pagination?	☒	☐	If NO, note deficiency on RPP-F-0013.
20. If the submitter has a manufacturing facility (contract or owned), and/or a sterilization facility (contract or owned), is the address(es) contained in the submission?	☒	☐	If NO, note deficiency on RPP-F-0013.
21. Does the submission contain a comparison table of the new device to the marketed device?	☒	☐	If NO, note deficiency on RPP-F-0013.
22. Does the submission contain information about the action taken to comply with voluntary standards?	☒	☐	If NO, note deficiency on RPP-F-0013.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00198

Checklist Questions:	YES	NO	Instructions
23. Does the submission contain performance data (can be bench or animal but not clinical), i.e.: Is there performance data for the marketed device? a. Bench testing? b. Animal testing?	☒ ☐ N/A	☐ ☐	If NO, note deficiency on RPP-F-0013.
Is there performance data for the new device? a. Bench testing? b. Animal testing?	☒ ☐ N/A	☐ ☐	If NO, note deficiency on RPP-F-0013.
24. If the device is labeled as sterile, does the submission contain sterilization data?	☒	☐	If NO, note deficiency on RPP-F-0013.
25. Does the device incorporate a computer or computer software?	☐ N/A	☐	If NO, note deficiency on RPP-F-0013.
a. If YES, is there information about the hardware?	☐ N/A	☐	
b. If YES, is there information about the software?	☐ N/A	☐	
26. a) Is there a specific guidance document for this type of device? Title: _____ _____ _____	☐	☒	If YES, continue review with checklist from the specific guidance document and return to question 27. If NO, proceed to question 26 b).
26 b) Contact the appropriate ODE Branch Chief to obtain information for reviewing this type of device. Has a summary of this discussion been documented?	☒	☐	If YES, answer question 27. If NO, do not proceed to question 27; stop review until summary completed.
27 Is this 510(k) sufficiently complete to allow substantive review?	☒	☐	If YES, continue review using specific guidance document or if no specific guidance document, continue the review using documentation forms. If NO, note deficiency on RPP-F-0013.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00199

510(k) Premarket Submission

Company:	**Children's Medical Ventures**
Product Name:	**Oral/Enteral Syringes**
Submittal Date:	**November 9, 2009**
Type of Submission:	**Traditional 510(k)**
Volume:	**1 of 1**

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00200

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Tab 4	Indications for Use Statement
Tab 5	510(k) Summary of Safety & Effectiveness
Tab 6	Truthful and Accuracy Statement
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Tab 11	Device Description (including Engineering Drawings)
Tab 12	Substantial Equivalence Discussion
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Tab 19	Performance Testing – Animal (N/A)
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00201

Authorization Form

Regulatory Technology Services LLC

Date: November 9, 2009

Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: Authorization for Accredited Person Review of 510(k)

To Whom It May Concern:

Enclosed is the Premarket Notification 510(k) for the following product:
Enteral/Oral Syringes manufactured by Children's Medical Ventures.

We at Children's Medical Ventures hereby authorize Regulatory Technology Services LLC to submit the enclosed 510(k) to the Food and Drug Administration (FDA) on our behalf, discuss its contents with the FDA, and function as the Accredited Person to perform the third party review.

We certify that we have not contacted another Accredited Person to perform the review of this 510(k) submission.

We accept the quote for 510(k) review services including the Regulatory Technology Services LLC Terms and Conditions.

Sincerely,

Matthew Young
Manager, Quality Assurance and Regulatory Affairs

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

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DJA 00202

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)*
11/09/2009	N/A (3rd party review)	unknown

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	Establishment Registration Number *(if known)*		
Philips Children's Medical Ventures	3007056120		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
NA	724-244-2624		
Street Address	**FAX Number *(including area code)***		
191 Wyngate Drive	412-380-8850		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Monroeville	PA	15146	USA
Contact Name			
Lisa Casavant			
Contact Title	**Contact E-mail Address**		
Regulatory Affairs Consultant	lisa.casavant@philips.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
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 301-796-8118

PSC Graphics (301) 443-1090 EF

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DJA 00203

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

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ 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)

- ☒ 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 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00204

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	KNT	2	FPD	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 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	K082654	1	Enteral Only Extension Set	1	Respironics Inc.
2	K060944	2	Nutrisafe 2 Transparent Syringes	2	Vygon Corp.
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

Gastrointestinal Tube and Accessories (Enteral Syringe)

	Trade or Proprietary or Model Name for This Device		Model Number
1	Oral/Enteral Syringes	1	N/A
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FPD	21 CFR 876.5980	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
Gastroenterology / Urology		

Indications *(from labeling)*

The Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00205

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)* unknown

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ 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 Sterilizer ☐ Contract Manufacturer ☐ 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 301-796-8118

Records processed under FOIA Request # 2016-1066; 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	10993-1	ISO	Biological evaluation of Medical Devices - Part 1: Evaluation and Testing	10993-1:2003	07/28/2003
2	ID54	ANSI/AAMI	Enteral feeding set connectors and adapters	1996/(R)2005	11/3/2006
3	11135-1	ANSI/ISO	Medical Devices – Validation and routine control of ethylene oxide sterilization	11135-1:2007(E)	11/1/2007
4	10993-7	ISO	Biological evaluation of medical devices – (b)(4) (b)(4)	10993-7:1995 (R) 2001	9/9/2008
5	11607-1	ISO	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	11607-1:2006	4/15/2006
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 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00207

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
Children's Medical Ventures

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Nov 9, 2009

3. ADDRESS *(Number, Street, State, and ZIP Code)*
191 Wyngate Drive
Monroeville, PA 15146

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 724-387-4012
(Fax) 412-380-8850

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)

Oral/Enteral Syringe

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) Matthew Young
(Title) Manager, Quality Assurance and Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
191 Wyngate Drive
Monroeville, PA 15146

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 724-387-4012
(Fax) 412-380-8850

15. DATE OF CERTIFICATION
Nov 9, 2009

PSC Graphics: (301) 443-1090 EF

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Instructions for Completion of Form FDA 3674

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))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. **& 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14.** - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 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 301-796-8118

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DJA 00209

November 9, 2009

Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

ATTN: Document Control Clerk
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

RE: 510(k) Notification, pursuant to 21 CFR807.90(e) for Children's Medical Ventures' Oral/Enteral Syringes

Dear Document Control Clerk:

Children's Medical Ventures (ChMV) hereby submits this **Traditional 510(k)** for Oral/Enteral Syringes. It is our conclusion, based on the information contained within this submittal, that the new device is safe and effective, and substantially equivalent to predicate devices.

In accordance with the FDA Guidance for Industry and FDA Staff Format for Traditional 510(k)'s, the following information is provided to address the principal factors of the design and use of the Oral/Enteral Syringes. This information is provided in tabular format, consistent with the requirements of this guidance.

Question	Yes	No
Is the device intended for prescription use (21CFR801 Subpart D)?	X	
Is the device intended for over-the-counter use (21CFR807 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	

Question	Yes	No
Is the device a reprocessed single use device?		X

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

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DJA 00210

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

We consider our intent to market this device as confidential commercial information and request that FDA treat it as such. We have taken precautions to protect the confidentiality of the intent to market this device. We understand that submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If you require additional information, please do not hesitate to contact me by phone or E-mail.

Sincerely,

Lisa Casavant

Primary Contact:
Name: Lisa Casavant
Title: Regulatory Affairs Consultant
Phone: 724-244-2624
Fax: 412-380-8850
Email: Lisa.Casavant@philips.com

Secondary Contact:
Name: Matthew Young
Title: Manager, Quality Assurance and Regulatory Affairs
Phone: 724-387-4012
Fax: 412-380-8850
Phone: Matthew.Young@phillips.com

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

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DJA 00211

Indications for Use

510(k) Number (if known): _____

Device Name: Oral/Enteral Syringes

Intended Use/Indications for Use:

Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk.

Patient Population/Environment of Use:

The patient population is neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral/Enteral Syringes are disposable and for single patient use only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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DJA 00212

TAB 5

510(K) SUMMARY

Date of Submission	11/9/09
Official Contact / Address of Manufacturing facility	Matthew Young Manager, Quality Assurance and Regulatory Affairs Children's Medical Ventures 191 Wyngate Drive Monroeville, PA 15146 Phone: 724-387-4012 Fax: 412-380-8850 Email: matthew.young@philips.com
Proprietary Name	Oral/Enteral Syringes
Common/Usual Name	Gastrointestinal tubes and accessories
Classification Reference	21 CFR 876.5980
Classification	Class II
Appropriate Classification Panel	Gastroenterology / Urology
Product Code	FPD
Predicate Devices	Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944) Respironics, Inc. Enteral Only Extension Set (K082654)

Intended Use/Indications for Use

The Oral/Enteral Syringes is intended for the delivery of liquid medication, formula, and breast milk.

Patient Population/Environment of Use

The patient population is neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral/Enteral Only Syringes is disposable and for single patient use only.

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

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DJA 00213

Substantial Equivalence

This traditional 510(k) submittal demonstrates that the Oral/Enteral Syringes are substantially equivalent to the Respironics, Inc. Enteral Only Extension Set (K082654) and the Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944).

Design verification tests were performed on the Oral/Enteral Syringes as a result of the risk analysis and product requirements. Testing Results demonstrated that the Oral/Enteral Syringes meet the required acceptance criteria. Children's Medical Ventures has determined that the Oral/Enteral Syringes are substantially equivalent to the predicate devices.

Device Description

The Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk. The syringes incorporate safety connectors that mate with the Respironics Enteral Only Extension Set, but will not mate with Luer lock or Luer slip fittings. The safety connectors prevent inadvertent connection of the enteral system to an IV system or an IV system to the enteral system.

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

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DJA 00214

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Manager of Quality Assurance and Regulatory Affairs of Children's Medical Ventures, 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.

(Signature)

Matthew Young

(Typed Name)

11-10-2009

(Date)

_____

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00215

TAB 7

CLASS III SUMMARY AND CERTIFICATION

This section does not apply. The ChMV Oral/Enteral Syringe device is Class II.

(End of Tab.)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00216

TAB 8

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

This section does not apply. No financial certification or disclosure statement is required since no clinical study was conducted for this submission.

(End of Tab.)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00217

TAB 9

DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

Commensurate with the FDA guidance titled **The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance, March 20, 1998**, the FDA guidance titled **Guidance on the Use of Standards in Substantial Equivalence Determinations; Guidance for Industry and FDA Staff, March 12, 2000**, and the FDA guidance titled **Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA Staff, June 20, 2001**, we are Declaring Conformity to the following list of standards and guidance documents recognized by FDA to establish a basis for safety and effectiveness for the ChMV Oral/Enteral Syringes:

- ISO 10993-1: 2003 "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing." Additional Data is located in TAB 15 – Biocompatibility Assessment
- ANSI/AAMI ID54:1996/(R)2001, "Enteral feeding set connectors and adapters" was followed in the design and development of the ChMV Oral/Enteral Syringes..

Summary Reports:

Declaration of Conformity to ISO 10993-1 and summary report follow.

(Please turn the page.)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00218

Declaration of Conformity to
ISO 10993-1 Biological evaluation of medical devices
Part 1: Evaluation and testing

We,

Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146, USA,

Declare that,

Component Certification

BARREL:
The barrel, used in the Oral/Enteral Syringe, made from polypropylene (b)(4), has been tested in accordance with the guidance provided in ISO-10993-1 for Surface Device– Mucosal membrane contact; Contact Duration A (Limited Contact (< 24 hrs). This requires that cytotoxicity, sensitization and irritation testing be performed. Test results ensured that this material successfully passes these type tests as specified by ISO-10993-1.

PISTON:
The piston, used in the Oral/Enteral Syringe, made from (b)(4) Silicone (b)(4) (b)(4), has been tested in accordance with the guidance provided in ISO-10993-1 for Surface Device– Mucosal membrane contact; Contact Duration A (Limited Contact (< 24 hrs). This requires that cytotoxicity, sensitization and irritation testing be performed. Test results ensured that this material successfully passes these type tests as specified by ISO-10993-1.

PLUNGER:
The plunger, used in the Oral/Enteral Syringe, made from Polypropylene ((b)(4), has been tested in accordance with the guidance provided in ISO-10993-1 for Surface Device– Mucosal membrane contact; Contact Duration A (Limited Contact (< 24 hrs). This requires that cytotoxicity, sensitization and irritation testing be performed. Test results ensured that this material successfully passes these type tests as specified by ISO-10993-1.

LUBRICANT:
The lubricant, used in the Oral/Enteral Syringe, made of (b)(4) (b)(4), has been tested in accordance with the guidance provided in ISO-10993-1 for Surface Device– Mucosal membrane contact; Contact Duration A (Limited Contact (< 24 hrs). This requires that cytotoxicity, sensitization and irritation testing be

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

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DJA 00219

performed. Test results ensured that this material successfully passes these type tests as specified by ISO-10993-1.

END CAP:
The end cap, used in the Oral/Enteral Syringe, made from (b)(4), has been tested in accordance with the guidance provided in ISO-10993-1 for Surface Device–Mucosal membrane contact; Contact Duration A (Limited Contact (< 24 hrs). This requires that cytotoxicity, sensitization and irritation testing be performed. Test results ensured that this material successfully passes these type tests as specified by ISO-10993-1.

MRY

11-10-2009

Matthew Young
Manager, Quality Assurance and Regulatory Affairs

Date

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

DJA 00220

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 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing, 2003

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 018	
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?	☒	☐
oes 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 the standard? 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: Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. FDA Reviewer's Guidance (#G95-1, 5/1/95)

[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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics (301)443-1090 EF

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

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DJA 00221

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
O 10993-1 BIOLOGICAL EVALUATION OF MEDICAL DEVICES -- PART 1: EVALUATION AND TESTING. 2003
.E SUMMARY REPORT PROVIDED FOR THIS STANDARD ON THE NEXT PAGE

CONFORMANCE WITH STANDARD SECTIONS*

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		

CTION 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.

* 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.

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

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DJA 00222

Oral/Enteral Syringe Summary Report

Conformance to ISO 10993-1: 2003 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

- Section 1: Scope
  No Requirements

- Section 2: Terms and Definitions
  No Requirements

  Section 2.1: Medical Device
  No Requirements

  Section 2.2: Material
  No Requirements

  Section 2.3: Final Product
  No Requirements

- Section 3: General Principles Applying to Biological Evaluation of Medical Devices

  Section 3.1:
  No Deviations. All materials used in the Oral/Enteral Syringe have either been cleared by the FDA or have been tested in accordance with the guidance provided by this standard. The test reports for these materials are available upon request.

  Section 3.2:
  No Deviations. See explanation included in Section 3.1.

  Section 3.3:
  No Deviations. See explanation included in Section 3.1.

  Section 3.4:
  No Deviations. See explanation included in Section 3.1.

  Section 3.5:
  No Deviations. See explanation included in Section 3.1.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00223

Section 3.6:
No Deviations. See explanation included in Section 3.1.

Section 3.7:
No Deviations. See explanation included in Section 3.1.

Section 3.8:
No Deviations. See explanation included in Section 3.1.

■ Section 4: Categorization of Medical Devices

Section 4.1: General
No Deviations

Section 4.2: Categorization by Nature of Body Contact

Section 4.2.1: Non-contact Devices
Not Applicable.

Section 4.2.2: Surface-contacting Devices
The materials used in the Oral/Enteral Syringe are classified as mucosal membrane contact.

Section 4.2.3: External Communicating Devices
Not Applicable.

Section 4.2.4: Implant Devices
Not Applicable.

Section 4.3: Categorization by Duration of Contact
The materials are for short-term use and as such as classified as limited contact duration (A).

■ Section 5: Testing

Section 5.1: General
No Deviations.

Section 5.2: Initial Evaluation Tests

Section 5.2.1: General
No Deviations.

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

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DJA 00224

Section 5.2.2: Cytotoxicity
No Deviations.

Section 5.2.3: Sensitization
No Deviations.

Section 5.2.4: Irritation
No Deviations.

Section 5.2.5: Intracutaneous Reactivity
No Deviations.

Section 5.2.6: Systemic Toxicity (Acute Toxicity)
Not Applicable.

Section 5.2.7: Subacute and Subchronic Toxicity
Not Applicable.

Section 5.2.8: Genotoxicity
Not Applicable

Section 5.2.9: Implantation
Not Applicable.

Section 5.2.10: Haemocompatibility
Not Applicable

Section 5.3: Supplementary Evaluation Tests

Section 5.3.1: General
No Deviations.

Section 5.3.2: Chronic Toxicity
Not Applicable.

Section 5.3.3: Carcinogenicity
Not Applicable.

Section 5.3.4: Reproductive and Developmental Toxicity
Not Applicable.

Section 5.3.5: Biodegradation
Not Applicable.

- Section 6: Selection of Biological Evaluation Tests

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00225

No Deviations. IN accordance with Table 1 in this standard and using the classification in Sections 4.2.2 and 4.3, testing for cytotoxicity, irritation and sensitization has been performed for all syringe materials.

- Section 7: Assurance of Test Methods

  Section 7.1: Test Method Assurance
  No Deviations.

  Section 7.2: Continued Assurance
  No Deviations.

- Annex A: Rationale
  Referenced as an informative guidance.

- Annex B: Flow Chart to aid in Ensuring a Systemic Approach to Biological Evaluation of Medical Devices
  Referenced as an informative guidance.

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

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

DJA 00226

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]

ANSI/AAMI ID54 Enteral feeding set connectors and adaptors

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# 9-31 List#016	
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]

[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 301-796-8118

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DJA 00227

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI ID 54 Enteral feeding set connectors and adaptors

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Please see below	Please see below	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

There were no deviations to the standard. All test results passed which demonstrated compliance with all requirements.

DESCRIPTION

JUSTIFICATION

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.

* 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.

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

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DJA 00228

TAB 10

EXECUTIVE SUMMARY

Date of Submission	November 9, 2009
Official Contact / Address of Manufacturing facility	Matthew Young Manager, Quality Assurance and Regulatory Affairs Children's Medical Ventures 191 Wyngate Dr. Monroeville, PA 15146 Phone: 724-387-4012 Fax: 412-380-8850
Establishment Registration Number	3007056120
Proprietary Name	Oral/Enteral Syringes
Common/Usual Name	Gastrointestinal tube and accessories (Enteral Syringe)
Classification Reference	21 CFR 876.5980
Classification	Class II
Appropriate Classification Panel	Gastroenterology / Urology
Product Code	FPD
Predicate Devices	Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944) Respironics, Inc. Enteral Only Extension Set (K082654)
Labeling	Draft labeling can be found in TAB 13
Intended Use	The Oral/Enteral Syringe is intended for the delivery of liquid medication, formula, and breast milk.
Reason for Submission	New Device

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00229

Substantial Equivalence

This traditional 510(k) submittal demonstrates that the Oral/Enteral Syringes are substantially equivalent to the Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944) and the Respironics Enteral Only Extension Set (K082654).

Design verification tests were performed on the Oral/Enteral Syringes as a result of the risk analysis and the product requirements. Verification testing demonstrated that the Oral/Enteral Syringes meet the required acceptance criteria and that all hazards were successfully mitigated.

Device Description

The Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk. The syringes incorporate safety connectors that mate with the Respironics Enteral Only Extension Set, but will not mate with Luer lock or Luer slip fittings. The safety connectors prevent inadvertent connection of the enteral system to an IV system or an IV system to the enteral system.

Material Description

The Oral/Enteral Syringes are comprised of four parts. The material used to manufacture each part is found in Table 5-1

Table 5-1 Materials used to manufacture the Oral/Enteral Only Syringes

Part	Material
Barrel	Polypropylene (b)(4)
Plunger	Polypropylene (b)(4)
Piston stopper (attaches to end of plunger to create seal)	(b)(4) Silicone (b)(4)
End Cap (attaches to output port of barrel)	(b)(4) Polyethylene (b)(4)

All materials have been evaluated in accordance with ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. A biocompatibility assessment of the materials is included in Section 15 of this submittal. The materials do not contain latex, DEHP, or BPA.

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

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DJA 00230

Performance Data

Design verification activities were performed on the Oral/Enteral Syringes as a result of the risk analysis and product requirements. All tests confirmed that the Oral/Enteral Syringes met the specified acceptance criteria. The Respironics Oral/Enteral Syringes comply with the applicable standards and requirements referenced in the following guidance documents and standards:

- ISO 10993-1:2003, Biological evaluation of Medical Devices – Part 1: Evaluation and Testing
- ANSI/AAMI ID54 1996, Enteral Feeding Set Adapters and Connectors.
- (b)(4) [redacted]
- ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices-Part 1: Requirements for materials, sterile barrier systems, and packaging systems.

In addition to this set of guidance/standards that was followed, supplemental supportive testing was performed as follows:

- Risk-based testing to assure that all hazards identified by the risk analysis are successfully mitigated (provided in Tab 18 of this submittal)
- Verification and validation testing to assure functionality of the device design and intended use (provided in Tabs 14 and 18 of this submittal)

Comparison to Predicate

A comparison of the Oral/Enteral Syringes to legally marketed predicate devices is provided in Tab 12.

(End of tab)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 002231

TAB 11

DEVICE DESCRIPTION

Physical Description and Usage

The Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk. The syringes incorporate safety connectors that mate with the Respironics Enteral Only Extension Set, but will not mate with Luer lock or Luer slip fittings. The safety connectors prevent inadvertent connection of the enteral system to an IV system or an IV system to the enteral system. The Oral/Enteral Syringes will be used in the hospital or home environment, by trained caregivers only.

Material Description

The Oral/Enteral Syringes are comprised of four parts. The material used to manufacture each part is found in Table 5-1

Table 5-1 Materials used to manufacture the Oral/Enteral Syringes

Part	Material
Barrel	Polypropylene (b)(4)
Plunger	Polypropylene (b)(4)
Piston stopper (attaches to end of plunger to create seal)	(b)(4) Silicone (b)(4)
End Cap (attached to output port of barrel)	(b)(4)

All materials have been evaluated in accordance with ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. A biocompatibility assessment of the materials is included in Section 15 of this submittal. The materials do not contain latex, DEHP, or BPA.

Engineering Drawings

Engineering drawings are provided on the following pages.

(Please turn the page)

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

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DJA 00232

RESPIRONICS

Respironics, Inc.
Component Specification Sheet (CSS) REF (b)(4) (b)(4)

CSS Document Number	Version	Document Description
(b)(4)	(b)(4)	1mL ORANGE ORAL SYRINGE

Approved Mfr.	Mfr. Description	Mfr. Part No.	Possible Dist.	Dist. Desc / PN
(b)(6)				

Specifications:

- Volumetric Accuracy below 0.2mL = +/-0.07ml
- Assemble the following PN's together (as shown below):
  (1) PN 1062687 – 1mL Orange Oral Syringe Barrel
  (1) PN 1062688 – 1mL Orange Oral Syringe Plunger
  (1) PN 1062689 – 1mL Oral Syringe Piston
  (1) PN 1062690 – Orange Oral Syringe End Cap
  ** Note: Place small amount of medical grade lubricant inside the 1mL Orange Oral Syringe Barrel (PN (b)(4)); excess lubricant should not be visible. **
- Place assembled Oral Syringe into a vendor supplied packaging; labeled per LBL# (b)(4). Package must support a sterile product for 4 years from date of manufacture.
- Lot and Use By dates must be present on the packaging
- Use By date must be in an YYYYMM format.

NOTE: Image is not to scale and for assembly illustration only. Some components may appear slightly different.

(b)(4) (b)(4) (b)(6)

Version Number	Revision History	Author

Refer to EDMS for Authorization and Approval Signatures

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

(b)(4) Manufacturer Information

(b)(4) Manufacturer Information

(b)(4) Manufacturer Information

(b)(4) Manufacturer Information

(b)(4) Manufacturer Information

(b)(4) Manufacturer Information

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DJA 00239

TAB 12

SUBSTANTIAL EQUIVALENCE DISCUSSION

Oral/Enteral Syringes are substantially equivalent to the Vygon Nutrisafe 2 System Transparent Syringes (K060944) and the Respironics Enteral Extension Set (K08254). (Note that ChMV and Respironics are both Phillips companies and may be used interchangeably in the submission and V&V documentation). Comparisons of the technical characteristics are shown in Table 12-1. Labeling for the Oral/Enteral Syringe and the predicate, Respironics Enteral Only Extension Set, is provided in Section 13. Labeling (package) for the predicate, Vygon Nutrisafe 2 System Transparent Syringes, could not be obtained; however product information was found on the manufacturer's web site (http://www.vygon.com/en/products/products.php?fam_id=435).

Comparison Discussion

The proposed device is an enteral syringe available in a series of volumes from 1 to 60 ml. There are two predicate devices: a syringe predicate and an extension set predicate. Predicate device #1, the Vygon Corporation Nutrisafe 2 System Transparent Syringe, is an enteral syringe available in multiple sizes ranging from 1 to 60 ml. The Vygon Syringe was 510(k) cleared as part of a feeding system (K060944).

Predicate device #2, the Respironics Enteral Only Extension Set (K082654), is intended for use as an extension set for nasogastric/oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors which reduce the risk of accidental connection of an I.V. system to the enteral system, or the enteral system to an I.V. system. The Respironics Enteral Only Extension Set and the proposed device are both manufactured by Philips.

The predicate devices and the proposed device are intended for use as part of feeding systems for neonates and infants. They all incorporate safety connectors which reduce the risk of accidental connection of an IV system to the enteral system, or the enteral system to an IV system.

The comparison table follows and can also be found in the Executive Summary (Tab 10) of this submission.

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

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DJA 00240

Table 10-2 Comparison of the ChMV Oral/Enteral Syringes with Predicate Devices

Note: Sources of the predicate device information were the 510(k) summary and the manufacturer's web site - http://www.vygon.com/en/products/products.php?fam_id=435.

	Predicate Device: Respironics Inc. Enteral Only Extension Set (K082654)	**Predicate Device:** Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944)	**Proposed Device:** ChMV Oral/Enteral Syringes
Intended use	The Enteral Only Extension Set is intended for use as an extension set for nasogastric/ oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors which reduce the risk of accidental connection of an I.V. system to the enteral system, or the enteral system to an I.V. system.	For nasogastric/oralgastric enteral feeding.	Oral/Enteral Syringe is Intended for delivery of liquid medication, formula, and breast milk.
Environment of Use	Hospital/institutional environment	Hospital, home, or environments where placement of a feeding tube is required	Hospital and home environment by trained caregivers only.
Patient Population	Pediatric and adult use	Neonates and Infants	Neonates and Infants
Product Code (Regulatory Description)	KNT	FPD	FPD
Patient Usage Type	Single use	Single use	Single use
Device Usage Type	Disposable	Disposable	Disposable
Design	Connects to enteral syringes and enteral extension sets	Connects to enteral feeding tubes or enteral extension sets	Connects to enteral feeding tubes or enteral extension sets
Non-IV Compatible Connector	Yes	Yes	Yes
Material	(b)	Unknown	Barrel & Plunger: *Polypropylene* (b)(4) Piston: (b)(4) *Silicone* (b)(4) End Cap: (b)(4)
Sizes	60" (152 cm) and 36" (91 cm)	1, 2, 5, 10, 20, and 60 ml	1, 3, 5, 10, 20, 30, and 60 ml
Sterility Condition	Sterile	Sterile	Sterile
Packaging Material	(b)(4) pouch	unknown	(b)(4) (b)(4)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00241

TAB 12

SUBSTANTIAL EQUIVALENCE DISCUSSION

Oral/Enteral Syringes are substantially equivalent to the Vygon Nutrisafe 2 System Transparent Syringes (K060944) and the Respironics Enteral Extension Set (K08254). (Note that ChMV and Respironics are both Phillips companies and may be used interchangeably in the submission and V&V documentation). Comparisons of the technical characteristics are shown in Table 12-1. Labeling for the Oral/Enteral Syringe and the predicate, Respironics Enteral Only Extension Set, is provided in Section 13. Labeling (package) for the predicate, Vygon Nutrisafe 2 System Transparent Syringes, could not be obtained; however product information was found on the manufacturer's web site (http://www.vygon.com/en/products/products.php?fam_id=435).

Comparison Discussion

The proposed device is an enteral syringe available in a series of volumes from 1 to 60 ml. There are two predicate devices: a syringe predicate and an extension set predicate. Predicate device #1, the Vygon Corporation Nutrisafe 2 System Transparent Syringe, is an enteral syringe available in multiple sizes ranging from 1 to 60 ml. The Vygon Syringe was 510(k) cleared as part of a feeding system (K060944).

Predicate device #2, the Respironics Enteral Only Extension Set (K082654), is intended for use as an extension set for nasogastric/oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors which reduce the risk of accidental connection of an I.V. system to the enteral system, or the enteral system to an I.V. system. The Respironics Enteral Only Extension Set and the proposed device are both manufactured by Philips.

The predicate devices and the proposed device are intended for use as part of feeding systems for neonates and infants. They all incorporate safety connectors which reduce the risk of accidental connection of an IV system to the enteral system, or the enteral system to an IV system.

The comparison table follows and can also be found in the Executive Summary (Tab 10) of this submission.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00242

Table 10-2 Comparison of the ChMV Oral/Enteral Syringes with Predicate Devices

Note: Sources of the predicate device information were the 510(k) summary and the manufacturer's web site - http://www.vygon.com/en/products/products.php?fam_id=435.

	Predicate Device: Respironics Inc. Enteral Only Extension Set (K082654)	**Predicate Device:** Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944)	**Proposed Device:** ChMV Oral/Enteral Syringes
Intended use	The Enteral Only Extension Set is intended for use as an extension set for nasogastric/ oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors which reduce the risk of accidental connection of an I.V. system to the enteral system, or the enteral system to an I.V. system.	For nasogastric/oralgastric enteral feeding.	Oral/Enteral Syringe is Intended for delivery of liquid medication, formula, and breast milk.
Environment of Use	Hospital/institutional environment	Hospital, home, or environments where placement of a feeding tube is required	Hospital and home environment by trained caregivers only.
Patient Population	Pediatric and adult use	Neonates and Infants	Neonates and Infants
Product Code (Regulatory Description)	KNT	FPD	FPD
Patient Usage Type	Single use	Single use	Single use
Device Usage Type	Disposable	Disposable	Disposable
Design	Connects to enteral syringes and enteral extension sets	Connects to enteral feeding tubes or enteral extension sets	Connects to enteral feeding tubes or enteral extension sets
Non-IV Compatible Connector	Yes	Yes	Yes
Material	(b)	Unknown	Barrel & Plunger: *Polypropylene*(b)(4)); Piston: (b)(4) *Silicone* (b)(4) End Cap: (b)(4))
Sizes	60" (152 cm) and 36" (91 cm)	1, 2, 5, 10, 20, and 60 ml	1, 3, 5, 10, 20, 30, and 60 ml
Sterility Condition	Sterile	Sterile	Sterile
Packaging Material	(b)(4) pouch	unknown	(b)(4) (b)(4))

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00243

TAB 13

PROPOSED LABELING

The Oral/Enteral Syringe labeling consists of the following:

- one-page insert in each box* of syringes,
- HIBC label on outer box* of syringes,
- artwork on the syringe itself,
- print on each individual syringe package.

*Note: The box holds multiple syringes and is the unit of sale.

Please turn the page for the Oral/Enteral Syringe labeling.

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

DJA 00244

Oral/Enteral Syringe

Caution! US federal law restricts this device to sale by or on the order or a physician.

Intended Use
Oral/Enteral Syringe is intended for the delivery of liquid medication, formula, and breast milk.

Manufactured for
Children's Medical Ventures, LLC
191 Wyngate Dr.
Monroeville, PA 15146

PHILIPS
Children's Medical Ventures

1068787
HM 10/22/09

Oral/Enteral Syringe

Caution! US federal law restricts this device to sale by or on the order or a physician.

Intended Use
Oral/Enteral Syringe is intended for the delivery of liquid medication, formula, and breast milk.

Manufactured for
Children's Medical Ventures, LLC
191 Wyngate Dr.
Monroeville, PA 15146

PHILIPS
Children's Medical Ventures

1068787
HM 10/22/09

Oral/Enteral Syringe

Caution! US federal law restricts this device to sale by or on the order or a physician.

Intended Use
Oral/Enteral Syringe is intended for the delivery of liquid medication, formula, and breast milk.

Manufactured for
Children's Medical Ventures, LLC
191 Wyngate Dr.
Monroeville, PA 15146

PHILIPS
Children's Medical Ventures

1068787
HM 10/22/09

Oral/Enteral Syringe

Caution! US federal law restricts this device to sale by or on the order or a physician.

Intended Use
Oral/Enteral Syringe is intended for the delivery of liquid medication, formula, and breast milk.

Manufactured for
Children's Medical Ventures, LLC
191 Wyngate Dr.
Monroeville, PA 15146

PHILIPS
Children's Medical Ventures

1068787
HM 10/22/09

(Box Insert)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00245

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
HIBC, 1ml, Orange Oral Syringe; Sterile	(b)(4)
LBL Revision Date: 10/27/2009	Sample attached

Specifications:

The package label shall meet the requirements states in Respironics document #(b)(4). The minimum label requirements are as follows:

Content:
[A] REF (b)(4) [REF artwork per RI/ChMV PN 309613]
[B] 1 ml, Orange Oral Syringe; Sterile
[C] ChMV Domestic address [RI/ChMV PN 309600]
[C] The text "Manufactured for" must be placed above the address block
[D] QTY: 100/box
[E] Shipping Symbols [RI/ChMV PNs 309282, 309283, and 309313]
[E] Made in China
[F] Temperature Range (Storage) [RI/ChMV PN 309301]
[F] Humidity [RI/ChMV PN 309304]
[G] Barcode [PER 80217] – NOTE: Code 39 is acceptable for the bar code
[H] LOT number and Expiration Date

Notes:
HIBC content can be printed directly onto the package container or onto a label and applied to the package container. Printing must be legible.

Layout per 80217 is recommended but not required. Font type and treatment, case (excluding product names) and punctuation for reference only.

RI PN indicates use of approved artwork on file. Artwork can be found in SAP or obtained by contacting RI. Typed text is not acceptable if RI artwork part number is referenced unless otherwise specified.

Trademark symbols are optional if they will not produce clearly.

Version Number	Record of Revision	Author
(b)(4)	Added label scan	(b)(6)
	Added shipping symbols	
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

DJA 00246

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

LOT 20091212
201311

Use By

REF 1062677

Manufactured for

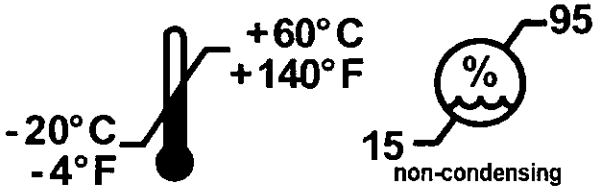
Children's Medical Ventures,LLC
191 Wyngate Drive
Monroeville,PA 15146 USA

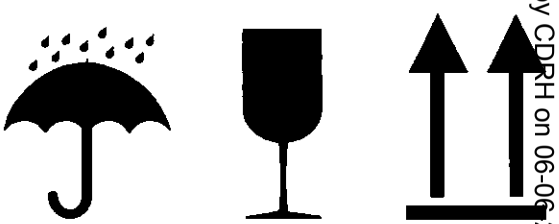
1ml, 1pc Orange Oral Syringe, Sterile

QTY: 100/box

MADE IN CHINA

+H90610626772/$20091212S





Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00247

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Printed,Package,1ml Amber Oral Syringe	(b)(4)
LBL Revision Date: 10/21/2009	**Page: 1 of 2**

Specifications:

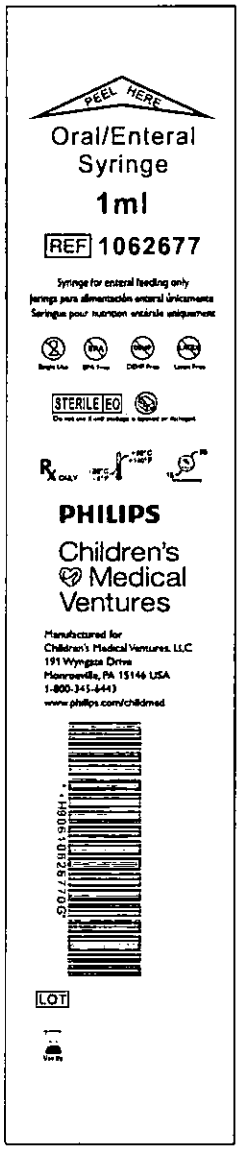
1) Material: (b)(4) or equivalent
2) Ink Color: Black
3) Size: See page 2
4) Artwork: See page 2

Version Number	Record of Revision	Author
(b)	Rearranged text and bar code; no content has been changed	(b)(6)
(b)	Initial Revision	

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016



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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00249

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Artwork, Orange Oral Syringe, 1ml	(b)(4)
LBL Revision Date: 8/10/2009	**Page 1 of 2**

Specifications:

See attached for artwork.

For reference only; artwork not to scale. Use best fit.

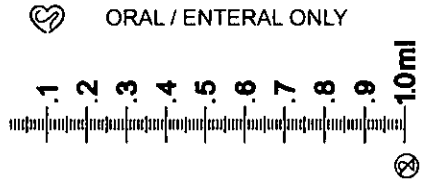
Version Number	Record of Revision	Author
(b)(4)	Added single use symbol; added enteral	(b)(6)
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00250



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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00251

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
HIBC, 3ml, Orange Oral Syringe; Sterile	(b)(4)
LBL Revision Date: 10/27/2009	**Sample attached**

Specifications:

The package label shall meet the requirements states in Respironics document (b)(4). The minimum label requirements are as follows:

Content:
[A] REF 1062678 [REF artwork per RI/ChMV PN 309613]
[B] 3 ml, Orange Oral Syringe; Sterile
[C] ChMV domestic address [RI/ ChMV PN 309600]
[C] The text "Manufactured for" must be placed above the address block
[D] QTY: 100/box
[E] Shipping Symbols [RI/ChMV PNs 309282, 309283, and 309313]
[E] Made in China
[F] Temperature Range (Storage) [RI/ChMV PN 309301]
[F] Humidity [RI/ ChMV PN 309304]
[G] Barcode [PER 80217] – NOTE: Code 39 is acceptable for the bar code
[H] LOT number and Expiration Date

Notes:
HIBC content can be printed directly onto the package container or onto a label and applied to the package container. Printing must be legible.

Layout per (b)(4) is recommended but not required. Font type and treatment, case (excluding product names) and punctuation for reference only.

RI PN indicates use of approved artwork on file. Artwork can be found in SAP or obtained by contacting RI. Typed text is not acceptable if RI artwork part number is referenced unless otherwise specified.

Trademark symbols are optional if they will not produce clearly.

Version Number	Record of Revision	Author
(b)(4)	Added label scan	(b)(6)
	Added shipping symbols	
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

DJA 00252

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

LOT 20091212
201311

Use By

REF 1062678

Manufactured for

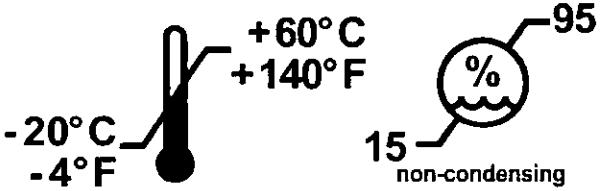
Children's Medical Ventures,LLC
191 Wyngate Drive
Monroeville,PA 15146 USA

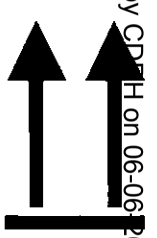
3ml, 1pc Orange Oral Syringe; Sterile

QTY: 100/box

MADE IN CHINA

+H9061062678Z/$20091212T





Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00253

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Printed,Package,3ml Orange Oral Syringe	(b)(4)
LBL Revision Date: 10/21/2009	**Page: 1 of 2**

Specifications:

1) Material: (b)(4) or equivalent
2) Ink Color: Black
3) Size: See page 2
4) Artwork: See page 2

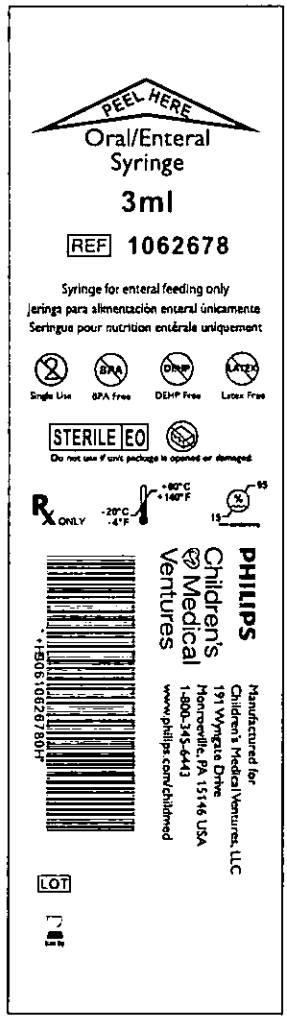
Version Number	Record of Revision	Author
(b)(4)	Rearranged text and bar code; no content has changed	(b)(6)
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00254



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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00255

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4) [redacted]

LBL Document Description	LBL Document Number
Artwork, Orange Oral Syringe, 3ml	(b)(4) [redacted]
LBL Revision Date: 8/10/2009	Page 1 of 2

Specifications:

See attached for artwork.

For reference only; artwork is not to scale. Use best fit.

Version Number	Record of Revision	Author
(b)(4) [redacted]	Added single use symbol; added enteral	(b)(6) [redacted]
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00256

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00257

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
HIBC, 5ml, Orange Oral Syringe; Sterile	(b)(4)
LBL Revision Date: 10/27/2009	**Sample attached**

Specifications:

The package label shall meet the requirements states in Respironics document (b)(4). The minimum label requirements are as follows:

Content:
[A] REF 1062679 [REF artwork per RI/ChMV PN 309613]
[B] 5 ml, Orange Oral Syringe; Sterile
[C] ChMV domestic address [RI/ ChMV PN 309600]
[C] The text "Manufactured for" must be placed above the address block
[D] QTY: 100/box
[E] Shipping Symbols [RI/ChMV PNs 309282, 309283, and 309313]
[E] Made in China
[F] Temperature Range (Storage) [RI/ChMV PN 309301]
[F] Humidity [RI/ ChMV PN 309304]
[G] Barcode [PER 80217] – NOTE: Code 39 is acceptable for the bar code
[H] LOT number and Expiration Date

Notes:
HIBC content can be printed directly onto the package container or onto a label and applied to the package container. Printing must be legible.

Layout per (b)(4) is recommended but not required. Font type and treatment, case (excluding product names) and punctuation for reference only.

RI PN indicates use of approved artwork on file. Artwork can be found in SAP or obtained by contacting RI. Typed text is not acceptable if RI artwork part number is referenced unless otherwise specified.

Trademark symbols are optional if they will not produce clearly.

Version Number	Record of Revision	Author
(b)(4)	Added label scan	(b)(6)
	Added shipping symbols	
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

DJA 00258

LOT 20091212
201311

Use By

REF 1062679

Manufactured for

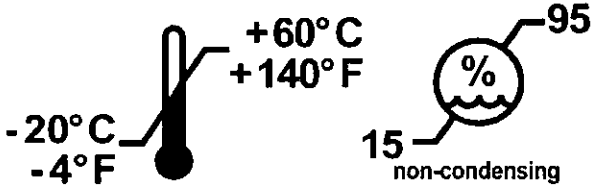
Children's Medical Ventures,LLC
191 Wyngate Drive
Monroeville,PA 15146 USA

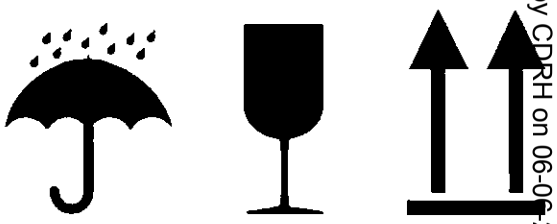
5ml, 1pc Orange Oral Syringe, Sterile

QTY: 100/box

MADE IN CHINA

+H90610626792/$20091212U





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

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Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 002559

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Printed,Package,5ml Orange Oral Syringe	(b)(4)
LBL Revision Date: 10/21/2009	**Page: 1 of 2**

Specifications:

1) Material: (b)(4) or equivalent
2) Ink Color: Black
3) Size: See page 2
4) Artwork: See page 2

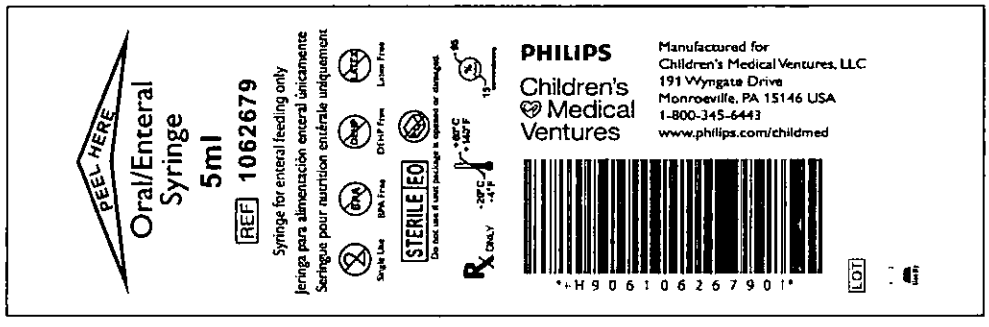
Version Number	Record of Revision	Author
(b)(4)	Rearranged text and bar code; no content changed	(b)(6)
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00260



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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00261

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Artwork, Orange Oral Syringe, 5ml	(b)(4)
LBL Revision Date: 8/10/2009	Page 1 of 2

Specifications:

See attached for artwork.

For reference only; artwork is not to scale. Use best fit.

Version Number	Record of Revision	Author
(b)(4)	Added single use symbol; added enteral	(b)(6)
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00262

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00263

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
HIBC, 10ml, Orange Oral Syringe; Sterile	(b)(4)
LBL Revision Date: 10/27/2009	Sample attached

Specifications:

The package label shall meet the requirements states in Respironics documen(b)(4) . The minimum label requirements are as follows:

Content:
[A] REF 1062680 [REF artwork per RI/ChMV PN 309613]
[B] 10 ml, 1 pc Orange Oral Syringe; Sterile
[C] ChMV domestic address [RI/ ChMV PN 309600]
[C] The text "Manufactured for" must be placed above the address block
[D] QTY: 100/box
[E] Shipping Symbols [RI/ChMV PNs 309282, 309283, and 309313]
[E] Made in China
[F] Temperature Range (Storage) [RI/ChMV PN 309301]
[F] Humidity [RI/ ChMV PN 309304]
[G] Barcode [PER 80217] – NOTE: Code 39 is acceptable for the bar code
[H] LOT number and Expiration Date

Notes:
HIBC content can be printed directly onto the package container or onto a label and applied to the package container. Printing must be legible.

Layout per(b)(4) is recommended but not required. Font type and treatment, case (excluding product names) and punctuation for reference only.

RI PN indicates use of approved artwork on file. Artwork can be found in SAP or obtained by contacting RI. Typed text is not acceptable if RI artwork part number is referenced unless otherwise specified.

Trademark symbols are optional if they will not produce clearly.

Version Number	Record of Revision	Author
(b)(4)	Added label scan	(b)(6)
	Added shipping symbols	
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

DJA 00264

LOT 20091212
201311

Use By

REF 1062680

Manufactured for

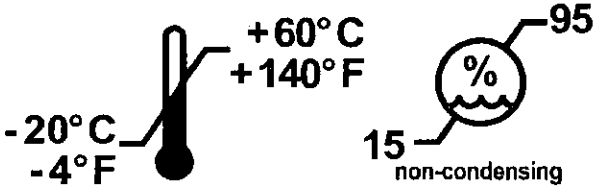
Children's Medical Ventures,LLC
191 Wyngate Drive
Monroeville,PA 15146 USA

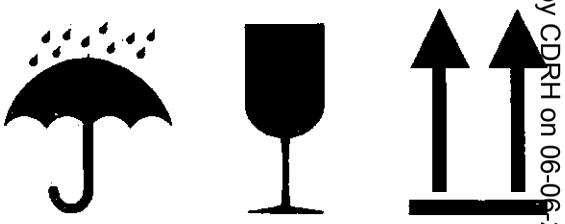
10ml,1pc Orange Oral Syringe, Sterile

QTY: 100/box

MADE IN CHINA

+H90610626802/$20091212M





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

Records processed under FOIA Request # 2016-1066, Released by CDRH on 06-06-2016

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00265

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Printed,Package,10ml Orange Oral Syringe	(b)(4)
LBL Revision Date: 8/16/2009	**Page: 1 of 2**

Specifications:

1) Material (b)(4)
2) Ink Color: Black
3) Size: See page 2
4) Artwork: See page 2

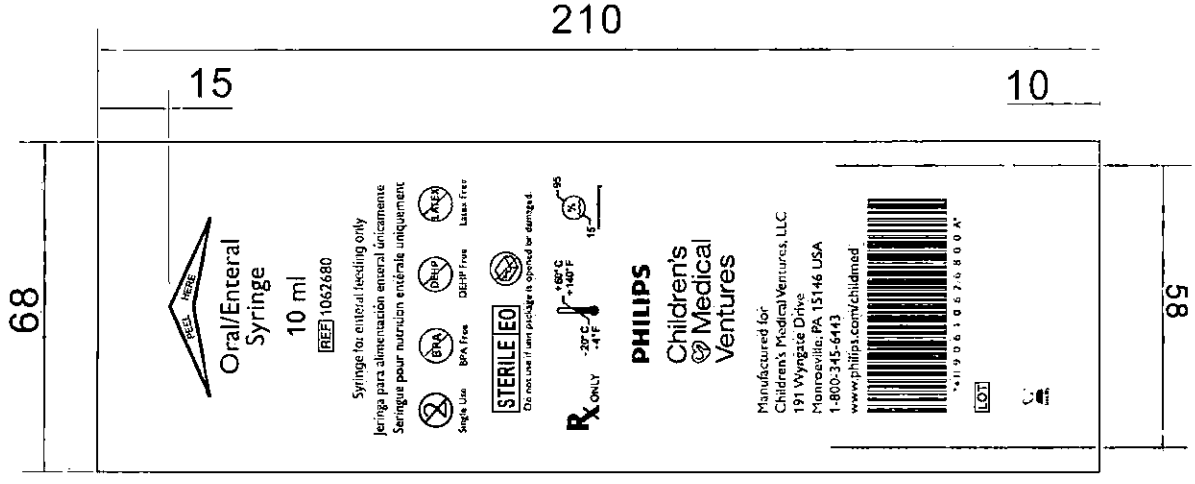
Version Number	Record of Revision	Author
(b)	Initial Revision	(b)(6)

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00266



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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00267

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Artwork, Orange Oral Syringe, 10ml	(b)(4)
LBL Revision Date: 8/10/2009	Page 1 of 2

Specifications:

See attached for artwork.

For reference only; artwork is not to scale. Use best fit.

Version Number	Record of Revision	Author
(b)(4)	Added single use symbol; added enteral	(b)(6)
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00268

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00269

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
HIBC, 20ml, Orange Oral Syringe; Sterile	(b)(4)
LBL Revision Date: 10/27/2009	Sample attached

Specifications:

The package label shall meet the requirements states in Respironics document (b)(4). The minimum label requirements are as follows:

Content:
[A] REF 1062681 [REF artwork per RI/ChMV PN 309613]
[B] 20 ml, 1pc Orange Oral Syringe; Sterile
[C] ChMV domestic address [RI/ ChMV PN 309600]
[C] The text "Manufactured for" must be placed above the address block
[D] QTY: 100/box
[E] Shipping Symbols [RI/ChMV PNs 309282, 309283, and 309313]
[E] Made in China
[F] Temperature Range (Storage) [RI/ChMV PN 309301]
[F] Humidity [RI/ ChMV PN 309304]
[G] Barcode [PER 80217] – NOTE: Code 39 is acceptable for bar code
[H] LOT number and Expiration Date

Notes:
HIBC content can be printed directly onto the package container or onto a label and applied to the package container. Printing must be legible.

Layout per (b)(4) is recommended but not required. Font type and treatment, case (excluding product names) and punctuation for reference only.

RI PN indicates use of approved artwork on file. Artwork can be found in SAP or obtained by contacting RI. Typed text is not acceptable if RI artwork part number is referenced unless otherwise specified.

Trademark symbols are optional if they will not produce clearly.

Version Number	Record of Revision	Author
(b)(4)	Added label scan	(b)(6)
	Added shipping symbols	
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

DJA 00270

LOT 20091212
201311

Use By

REF 1062681

Manufactured for

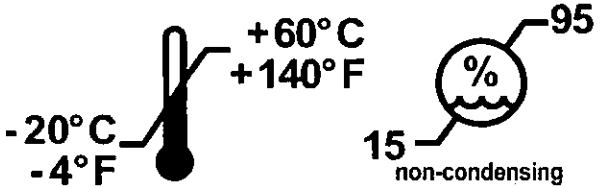
Children's Medical Ventures,LLC
191 Wyngate Drive
Monroeville,PA 15146 USA

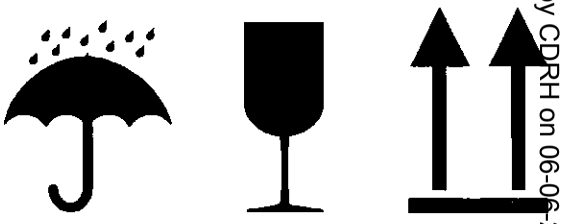
20ml,1pc Orange Oral Syringe, Sterile

QTY: 100/box

MADE IN CHINA

+H90610626812/$20091212N





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

Records processed under FOIA Request # 2016-1066, Released by CDRH on 06-06-2016

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 002271

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Printed,Package,20ml Orange Oral Syringe	(b)(4)
LBL Revision Date: 8/16/2009	**Page: 1 of 2**

Specifications:

1) Material: (b)(4)
2) Ink Color: Black
3) Size: See page 2
4) Artwork: See page 2

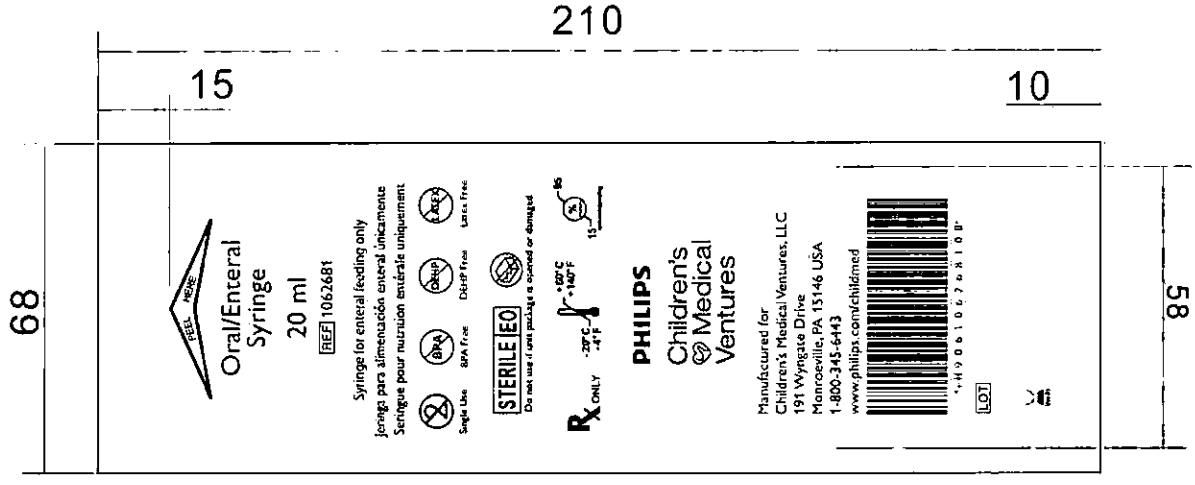
Version Number	Record of Revision	Author
(b)	Initial Revision	(b)(6)

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00272



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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00273

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Artwork, Orange Oral Syringe, 20ml	(b)(4)
LBL Revision Date: 8/10/2009	**Page 1 of 2**

Specifications:

See attached for artwork.

For reference only; artwork is not to scale. Use best fit.

Version Number	Record of Revision	Author
(b)(4)	Added single use symbol; added enteral	(b)(6)
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00274

ORAL / ENTERAL ONLY

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00275

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
HIBC, 30ml, Orange Oral Syringe; Sterile	(b)(4)
LBL Revision Date: 10/27/2009	Sample attached

Specifications:

The package label shall meet the requirements states in Respironics document (b)(4). The minimum label requirements are as follows:

Content:
[A] REF 1062682 [REF artwork per RI/ChMV PN 309613]
[B] 30 ml, 1 pc Orange Oral Syringe; Sterile
[C] ChMV domestic address [RI/ ChMV PN 309600]
[C] The text "Manufactured for" must be placed above the address block
[D] QTY: 100/box
[E] Shipping Symbols [RI/ChMV PNs 309282, 309283, and 309313]
[E] Made in China
[F] Temperature Range (Storage) [RI/ChMV PN 309301]
[F] Humidity [RI/ ChMV PN 309304]
[G] Barcode [PER 80217] – NOTE: Code 39 is acceptable for the bar code
[H] LOT number and Expiration Date

Notes:
HIBC content can be printed directly onto the package container or onto a label and applied to the package container. Printing must be legible.

Layout per (b)(4) is recommended but not required. Font type and treatment, case (excluding product names) and punctuation for reference only.

RI PN indicates use of approved artwork on file. Artwork can be found in SAP or obtained by contacting RI. Typed text is not acceptable if RI artwork part number is referenced unless otherwise specified.

Trademark symbols are optional if they will not produce clearly.

Version Number	Record of Revision	Author
(b)(4)	Added label scan	(b)(6)
	Added shipping symbols	
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

DJA 00276

LOT 20091212
201311

Use By

REF 1062682

Manufactured for

Children's Medical Ventures, LLC
191 Wyngate Drive
Monroeville, PA 15146 USA

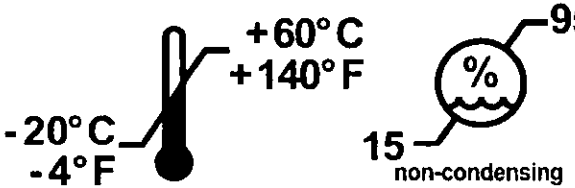
30ml, 1pc Orange Oral Syringe

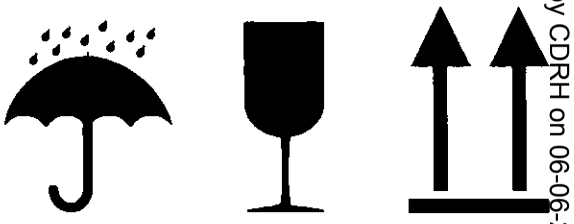
Sterile

QTY: 100/box

MADE IN CHINA

+H90610626822/$200912120





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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00277

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF [redacted]
b

LBL Document Description	LBL Document Number
Printed,Package,30ml Orange Oral Syringe	(b)(4) [redacted]
LBL Revision Date: 8/16/2009	Page: 1 of 2

Specifications:

1) Material: (b)(4) [redacted]
2) Ink Color: Black
3) Size: See page 2
4) Artwork: See page 2

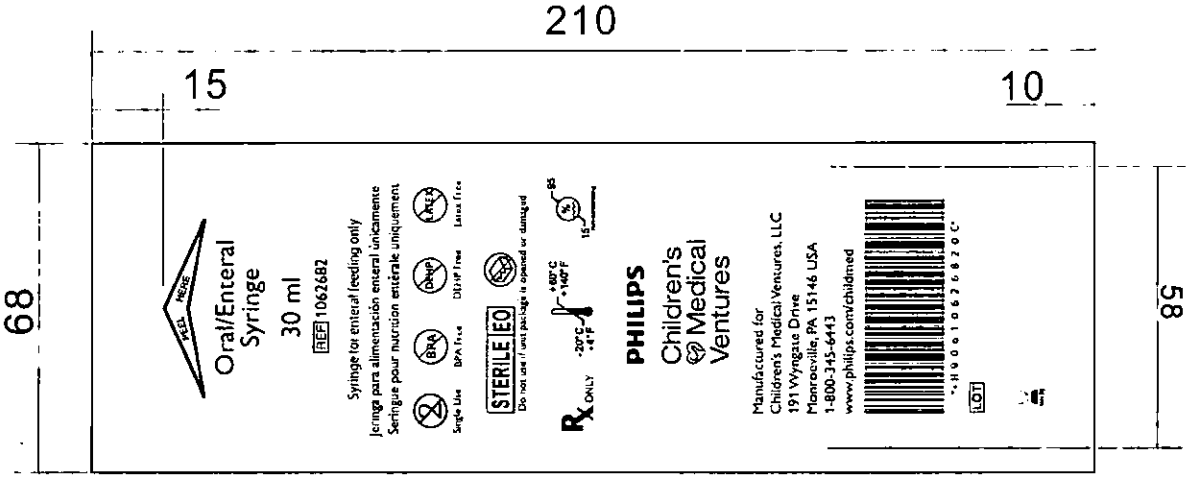
Version Number	Record of Revision	Author
(b) [redacted]	Initial Revision	(b)(6) [redacted]

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00278



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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 002279

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Artwork, Oral Dispenser, 30ml	(b)(4)
LBL Revision Date: 8/10/2009	Page 1 of 2

Specifications:

See attached for artwork.

For reference only; artwork is not to scale. Use best fit.

Version Number	Record of Revision	Author
(b)(4)	Added single use symbol; added enteral	(b)(6)
	Initial Revision	

Refer to EDMS for Authorization and Approval

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

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DJA 00280

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00281

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
HIBC 60ml, Orange Oral Syringe; Sterile	(b)(4)
LBL Revision Date: 10/27/2009	Sample attached

Specifications:

The package label shall meet the requirements states in Respironics document (b) ( ). The minimum label requirements are as follows:

Content:
[A] REF 1062683 [REF artwork per RI/ChMV PN 309613]
[B] 60 ml, 1pc Orange Oral Syringe; Sterile
[C] ChMV domestic address [RI PN 309600]
[C] The text "Manufactured for" must be placed above the address block
[D] QTY: 100/box
[E] Shipping Symbols [RI/ChMV PNs 309282, 309283, and 309313]
[E] Made in China
[F] Temperature Range (Storage) [RI/ChMV PN 309301]
[F] Humidity [RI PN 309304]
[G] Barcode [PER (b)(4)] - NOTE: Code 39 is acceptable for the bar code
[H] LOT number and Expiration Date

Notes:
HIBC content can be printed directly onto the package container or onto a label and applied to the package container. Printing must be legible.

Layout per (b)(4) is recommended but not required. Font type and treatment, case (excluding product names) and punctuation for reference only.

RI PN indicates use of approved artwork on file. Artwork can be found in SAP or obtained by contacting RI. Typed text is not acceptable if RI artwork part number is referenced unless otherwise specified.

Trademark symbols are optional if they will not produce clearly.

Version Number	Record of Revision	Author
(b)(4)	Added label scan	(b)(6)
	Added shipping symbols	
	Initial Revision	

Refer to EDMS for Authorization and Approval

DJA 00282

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

LOT 20091212
201311

Use By

REF 1062683

Manufactured for

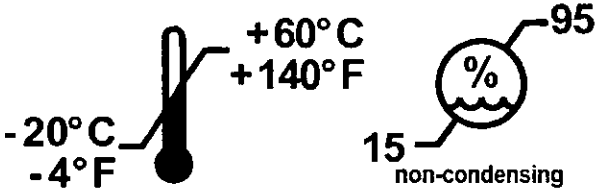
Children's Medical Ventures,LLC
191 Wyngate Drive
Monroeville,PA 15146 USA

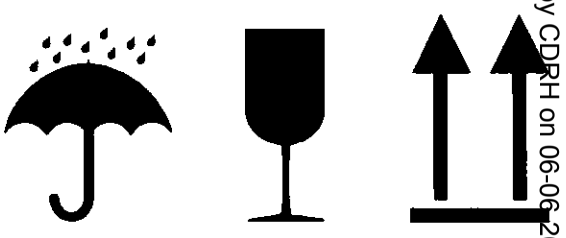
60ml,1pc Orange Oral Syringe, Sterile

QTY: 100/box

MADE IN CHINA

+H90610626832/$20091212P





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Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00283

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Printed,Package,60ml Orange Oral Syringe	(b)(4)
LBL Revision Date: 8/16/2009	Page: 1 of 2

Specifications:

1) Material: (b)(4)
2) Ink Color: Black
3) Size: See page 2
4) Artwork: See page 2

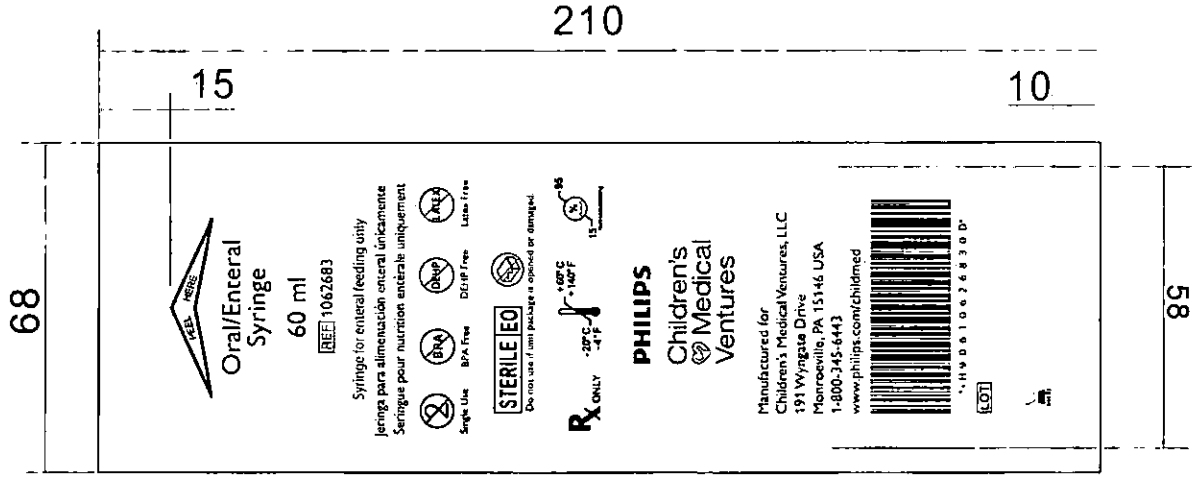
Version Number	Record of Revision	Author
(b)	Initial Revision	(b)(6)

Refer to EDMS for Authorization and Approval

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00284



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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00285

RESPIRONICS

Respironics, Inc.
Labeling Specification Sheet (LBL)

REF (b)(4)

LBL Document Description	LBL Document Number
Artwork, Orange Oral Syringe, 60ml	(b)(4)
LBL Revision Date: 8/10/2009	Page 1 of 2

Specifications:

See attached for artwork.

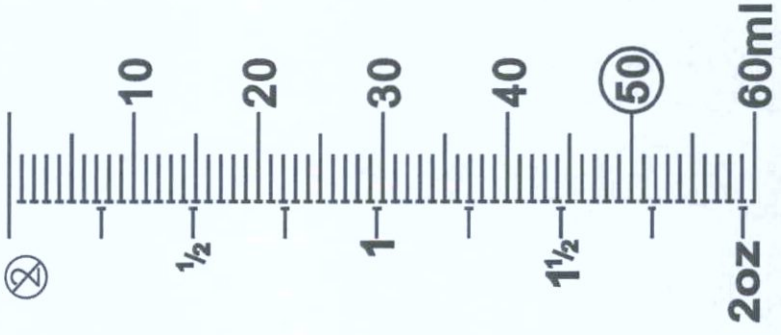
For reference only; artwork is not to scale. Use best fit.

Version Number	Record of Revision	Author
(b)(4)	Added single use symbol; added enteral	(b)(6)
	Initial Revision	

Refer to EDMS for Authorization and Approval

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00286



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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00287

TAB 14

STERILIZATION

As suggested by the Updated 510(k) Sterility Review Guidance, K90-1, dated 8/30/02, the following information is provided on the traditional method of sterilization used to process the Respironics, Inc. Enteral Only Extension Sets.

Sterilization method:

(b)(4)

Method used to validate the sterilization cycle:

(b)(4)

(End of tab)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00288

TAB 15

BIOCOMPATIBILITY ASSESSMENT

The materials used in the Oral/Enteral Syringe were assessed for biocompatibility in accordance with ISO 10993-1:2003. Please refer to Tab 9 for the Declaration of Conformity to ISO 10993-1:2003. Per the testing guidelines in ISO 10993-1, the syringe falls under the surface device category, mucosal membrane contact, and limited contact duration ("A" - less than 24 hours). In accordance with those criteria, cytotoxicity, sensitization, and irritation tests were performed. The biocompatibility test report is provided on the following pages.

Table 15-1: The table provides information on each of the materials used to construct Oral/Enteral Syringe.

Oral/Enteral Syringe Component	Type of Patient Contact	Contact with feeding solution?	Material
Barrel	Indirect	Yes	Polypropylene (b)(4)
Plunger	Indirect	No	Polypropylene (b)(4)
Piston (attaches to end of plunger to create seal)	Indirect	Yes	(b)(4) Silicone (b)(4)
Lubricant	Indirect	Yes	(b)(4)
End Cap (attached to output port of barrel)	Indirect	No	(b)(4)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00289

RESPIRONICS

Philips Children's Medical Ventures

Oral/Enteral Syringe Biocompatibility Assessment Report

Version (b)

(b)(4)

Prepared for:

Philips Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

Prepared by:

Lisa Casavant

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Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

ER# [redacted]
b

Revision History

DOCUMENT REVISION RECORD				
Version	Date	Pages	Description	Contributors
[redacted]	10/09/09	All	Original release of document.	L. Casavant
Notes:				

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00290

- Contents -

1.0 INTRODUCTION
- 1.1 Purpose
- 1.2 Scope
- 1.3 References

2.0 ASSESSMENT METHODOLOGY

3.0 CATEGORIZATION AND TEST DETERMINATION

4.0 BIOCOMPATIBILITY TEST RESULTS

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

(b)(4)

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

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

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(b)(4) Third Party Testing

(b)(4) Third Party Testing

DJA 00353

Appendix B1 - Component Parts Materials Table

Oral/Enteral Syringe

Component	Material	Testing or Analysis performed
Barrel	The barrel is polypropylene (b)(4) Color: *1 ml-* Orange (b)(4) (b)(4) *5 ml–60 ml-* Transparency	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
Piston	The piston is (b)(4) (b)(4) Silicone (b)(4) (b)(4) Color: Black	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
Plunger	The plunger is polypropylene (b)(4) Color: *1 ml-* White *5 ml-60 ml-* Orange (b)(4)	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
Lubricant	The syringe lubricant is (b)(4)	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
End Cap	The end cap is (b)(4) (b)(4) Color: Orange (b)(4) (b)(4)	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}

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

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Appendix B1 - Component Parts Materials Table

Oral/Enteral Syringe

All of the components of the Oral/Enteral Syringe have been classified as Category A (< 24 hrs). The materials are defined as mucosal membrane contact. They have no direct contact to any breached or compromised surfaces. They do not contact the blood path indirectly, nor do they contact circulating blood as defined by ISO 10993-1.

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

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DJA 00355

TAB 16

SOFTWARE INFORMATION

Does not apply. Oral/Enteral Syringes are not software-driven electronic devices.

(End of tab)

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

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DJA 00356

TAB 17

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

Does not apply. The Oral/Enteral Syringes are not electrically powered devices.

(End of tab)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00357

TAB 18

PERFORMANCE TESTING – BENCH

Performance testing was performed on the Oral/Enteral Syringes to verify compliance to the design specifications.

Risk Analysis

A risk analysis was conducted in accordance with the guidance provided in ISO 14971: 2007 Medical Devices – Application of Risk Management to Medical Devices, to consider and mitigate all hazards associated with use of the Oral/Enteral Syringes. (b)(4)

(b)(4)

Design Verification Testing

The design verification test plan, procedure and report provides a summary of the test methods and results used to verify functionality of the Oral/Enteral Syringes as it relates to the product requirements and the risk analysis.

(b)(4)

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

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DJA 00358

Summary

The following information is included in this section:

- Design V&V Plan, Procedure, and Report
- Risk Analysis

(Please turn the page.)

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

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DJA 00359

Tab 18A

Design V&V Plan, Procedure, and Report

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

RESPIRONICS®

DESIGN V&V REPORT SPECIFICATION

Oral/Enteral syringe

ER#: (b)(4) Manufactur

Version#: (b)(4)

Prepared by: (b)(6)

Respironics, Inc.
Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

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

DJA 00360

(b)(4) Design V&V Report Specification

(b)(4) Design V&V Report Specification

(b)(4) Design V&V Report Specification

(b)(4) Design V&V Report Specification

(b)(4) Design V&V Report Specification

(b)(4) Design V&V Report Specification

(b)(4) Design V&V Report Specification

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00368

RESPIRONICS®

11/2009
Original Results

Oral/Enteral syringe

TEST PROCEDURE SPECIFICATION

Oral/Enteral syringe

ER#(b)(4) Test Procedure

Version#: (b) (4)

Prepared by: (b)(6)

Respironics, Inc.
Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

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(b)(4) Test Procedure Specification

(b)(4) Test Procedure Specification

(b)(4) Test Procedure Specification

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DJA 00404

Philips/ChMV Oral/Enteral Syringe Dimensional Analysis and Compliance to ANSI/AAMI ID 54:1996/(R)2005

ISO 594/1 and ISO 594/2 outline specifications for conical fittings with a 6% (Luer) taper for syringes, needles and certain medical equipment. Part 1 specifies general requirements and Part 2 outlines specifications regarding the lock fittings. The ChMV Oral/Enteral Syringes are specifically designed to NOT function with either of these fittings to avoid dangerous feeding and medication errors that can pose a significant risk to the infant and the hospital.

As a means to justify and validate that Oral/Enteral Syringes in fact do not mate and or function with devices containing Luer Lock or Luer Slip connections, a dimensional analysis was completed using the dimensional data of each size Oral/Enteral Syringes barrel and cross-referencing those dimensions against Table 1 of ISO 594/1. The only dimensions that are critical to analyze in this instance are the range of acceptable diameters measured at the end of the male conical fitting and at the opening of a female conical fitting. Below is a summary of the noted results.

Reference		Designation	Dimensions (mm)	
			ISO Standard Semi - Rigid material	Philips/ChMV Syringe
Basic Dimensions	d	diameter at the end of the male conical fitting *see figure A*	*min = 3.925* *max = 4.027*	4.8
	D	diameter at the opening of the female conical fitting *see figure B*	min = 4.270 max = 4.315	acceptable range is much smaller than the 4.8mm dimension taken from the tip of the Philips/ChMV syringe

Figure A

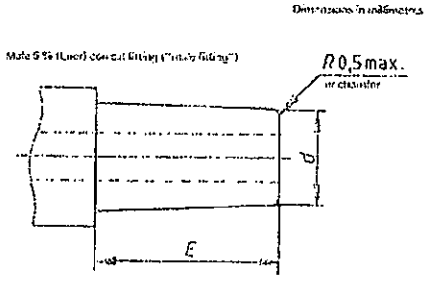
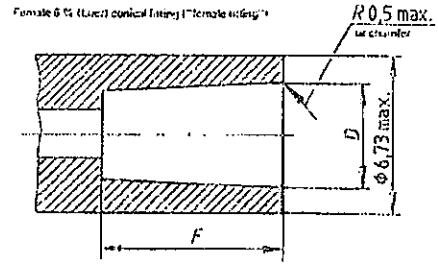


Figure B



As noted above, the range of acceptable dimensions for a semi-rigid Luer conical fittings is 3.925 -4.027mm measured at the end of the male conical fitting (reference figure A). Philips ChMV Oral Syringe specification sheets specify a dimension of 4.8mm measured at the end of the syringe tips (conical fitting) which is larger than allowed by the ISO standard. Additionally, the standard specifies the range of acceptable dimensions measured at the opening of the female conical fitting (reference figure B). This acceptable range as shown in the above chart is much smaller than the 4.8mm male tip dimension of the Oral/Enteral Syringes creating an impossible mating condition.

This dimensional analysis demonstrates that ChMV Oral/Enteral Syringes not compatible with Luer slip or Luer lock connections.

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

(b)(4) Test Procedure Specification

(b)(4) Test Procedure Specification

(b)(4) Test Procedure Specification

(b)(4) Test Procedure Specification

(b)(4) Test Procedure Specification

(b)(4) Test Procedure Specification

(b)(4) Test Procedure Specification

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(b)(4) Test Procedure Specification

(b)(4) Test Procedure Specification

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DJA 00417

Tab 18B

Risk Analysis

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00418

RESPIRONICS

Oral/Enteral Syringes

Risk Assessment

(b)(4)

Version (b)

Prepared for:

Children's Medical Ventures
RESPIRONICS INC.
191 Wyngate Drive
Monroeville, PA 15146

Prepared by:

(b)(6)

CONFIDENTIAL

(b)(4)

All Rights Reserved

DA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00419

Version History

Date	Version	Description	Contributors
09/29/09	00	Initial Release.	(b)(6)
10/07/09	(b)(4)		
11/10/09			

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Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00420

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(b)(4) Risk Assessment

(b)(4) Risk Assessment

(b)(4) Risk Assessment

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(b)(4) Risk Assessment

(b)(4) Risk Assessment

(b)(4) Risk Assessment

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00437

TAB 19

PERFORMANCE TESTING - ANIMAL

No performance testing on animals was required for the Oral/Enteral Syringes.

(End of tab)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00438

TAB 20

PERFORMANCE TESTING - CLINICAL

No clinical evaluation is required for the Oral/Enteral Only Syringes. Please refer to Section 18 of this submittal for the verification test plan, procedure and report.

(End of tab)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00004

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Jeffrey Cooperson

Subject: 510(k) Number K100099/S2

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/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 N, 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.)			✓

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00005

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
21 CFR 876.5980	II	FPD

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Carolyn Y Neuland (Branch Chief) GRDB (Branch Code) 6/10/10 (Date)

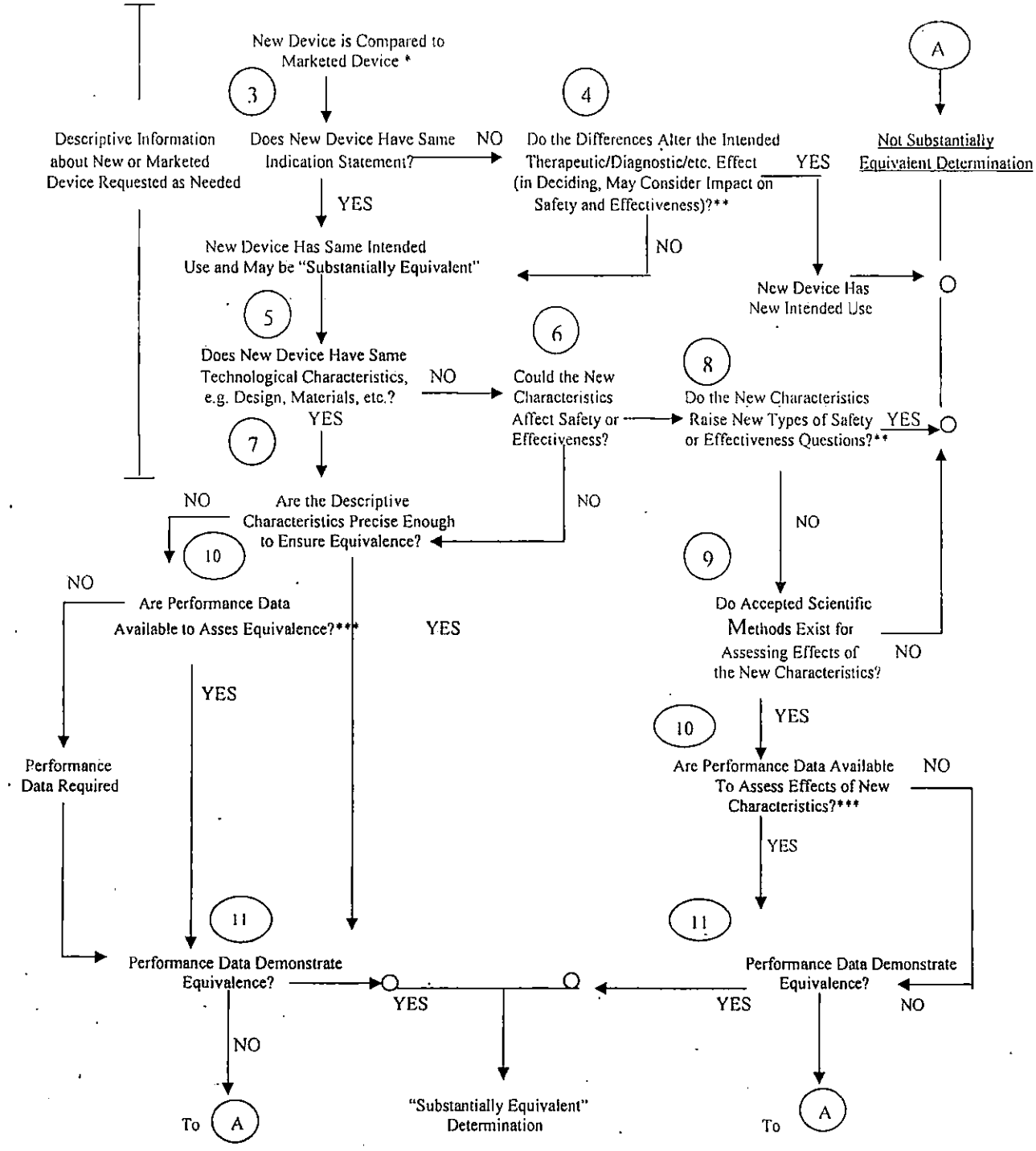
Final Review: _____ (Division Director) 6/14/10 (Date)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00006

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 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00007

MEMORANDUM
Office of Device Evaluation
DRARD/GRDB

Subject: K100099-S2

Date: June 9, 2010

Device: Phillips Children's Medical Ventures, LLC

Company: Library Medical

To: Carolyn Neuland, PhD
Branch Chief

From: Jeffrey Cooper, M.S., D.V.M.
GRDB Veterinary Medical Officer

This is a third party reviewed pediatric enteral feeding syringe.

On the original submission I had found that (b)(4) [redacted]

Supplement 1 provided responses to those two deficiencies. (b)(4) [redacted] This is adequate.

The bench testing [redacted] (b)(4) [redacted]

My concern was that (b)(4) [redacted]

I spoke to Mark Job, the 3rd party reviewer. He requested more information on the (b)(4) [redacted] (b)(4) [redacted] I told him that this submission will be placed on telephone hold.

Supplement 2 is the root cause investigation outcome. The response is:

(b)(4) Deficiencies [redacted]

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00008

This appears to be an adequate solution to address the problem.

I concur with the SE recommendation.

Jeffrey Cooper, M.S., D.V.M.

C Neuland
6/10/10

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00009

	510(k) SUMMARY REQUIREMENTS CHECKLIST 21 CFR 807.92 K100099			
	All 510(k) summaries shall contain the following information:	Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared	√		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	√		
3	An identification of the legally marketed device(s) to which the submitter claims equivalence.	√		
4	A description of the device that is the subject of the 510(k), including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)	√		
5	A statement of the indications for use of the device that is the subject of the 510(k), including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is indicated. Or, if the indication statements are different from those of the legally marketed device(s) identified in paragraph (3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device, and why the differences do not affect the safety and effectiveness of the device when used as indicated.	√		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source, etc.) as the predicate device(s) identified in paragraph(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified in paragraph (3) of this section.	√		
	510(k) summaries for those 510(k)s in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information			
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence	√		
8	A summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. (There can not be any patient identifier information in the summary.)			√
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in paragraph(3) of this section.	√		

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 000110

Cooper, Jeffrey (CDRH)

From: MARK JOB [mark@markjob.com]
Sent: Thursday, June 10, 2010 4:16 PM
To: Cooper, Jeffrey (CDRH)
Subject: RE: K100099
Attachments: K100099 510k Summary_revised 6-10-2010.doc

Hello Jeffery,

Attached is the revised 510(k) summary.

The modifications meet the intent of 21 CFR 807.92.

Please let me know you have any questions.

Best regards,

Mark

Mark Job
Reviewer
Regulatory Technology Services LLC
Phone: 763 682 4139
FAX: 763 682 4420
Email: mark@markjob.com

From: Cooper, Jeffrey (CDRH) [mailto:Jeffrey.Cooper@fda.hhs.gov]
Sent: Thursday, June 10, 2010 9:30 AM
To: MARK JOB
Subject: RE: K100099

Mark-

(b)(4) Deficiencies [redacted]

They should also (b)(4) Deficiencies [redacted]

Jeffrey Cooper, M.S., D.V.M.

From: MARK JOB [mailto:mark@markjob.com]
Sent: Friday, June 04, 2010 10:47 AM
To: Cooper, Jeffrey (CDRH)
Subject: RE: K100099

Hi Jeffrey,

[redacted] Thanks for the response.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00011

Best regards,

Mark Job
Reviewer
Regulatory Technology Services LLC
Phone: 763 682 4139
FAX: 763 682 4420
Email: mark@markjob.com

From: Cooper, Jeffrey (CDRH) [mailto:Jeffrey.Cooper@fda.hhs.gov]
Sent: Friday, June 04, 2010 9:23 AM
To: MARK JOB
Subject: RE: K100099

Mark-

Thank you. This appears to adequately answer the question.

Jeffrey Cooper, M.S., D.V.M.
Veterinary Medical Officer
Center for Devices & Radiological Health (CDRH)
Office of Device Evaluation (ODE)
Division of Reproductive, Abdominal and Radiological Devices (DRARD)
Gastroenterology and Renal Devices Branch (GRDB)
WO66 G228
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
(301) 796-6517
jeffrey.cooper@fda.hhs.gov

From: MARK JOB [mailto:mark@markjob.com]
Sent: Thursday, June 03, 2010 10:30 AM
To: Cooper, Jeffrey (CDRH)
Subject: RE: K100099

Hello Jeffrey,

In response to the telephone conversation the sponsor has provided additional information related to the corrective action taken to correct the problem of (b)(4) Deficiencies [redacted] Attached is their response.

The original and one copy will delivered to the DMC tomorrow morning.

Please contact me if you have further questions.

Best regards,

Mark

Mark Job
Reviewer
Regulatory Technology Services LLC

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00012

Phone: 763 682 4139
FAX: 763 682 4420
Email: mark@markjob.com

From: Cooper, Jeffrey (CDRH) [mailto:Jeffrey.Cooper@fda.hhs.gov]
Sent: Friday, January 22, 2010 3:38 PM
To: mark@markjob.com
Subject: K100099

Mark Job-

I have looked at your review of K100099 and I have a few questions. (b)(4) Deficiencies

(b)(4) Deficiencies

Thanks,

Jeffrey Cooper, M.S., D.V.M.
Veterinary Medical Officer
Center for Devices & Radiological Health (CDRH)
Office of Device Evaluation (ODE)
Division of Reproductive, Abdominal and Radiological Devices (DRARD)
Gastroenterology and Renal Devices Branch (GRDB)
WO66 G228
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
(301) 796-6517
jeffrey.cooper@fda.hhs.gov

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00013

TAB 5

510(K) SUMMARY

Date of Submission	11/9/09
Official Contact / Address of Manufacturing facility	Matthew Young Manager, Quality Assurance and Regulatory Affairs Children's Medical Ventures 191 Wyngate Drive Monroeville, PA 15146 Phone: 724-387-4012 Fax: 412-380-8850 Email: matthew.young@philips.com
Proprietary Name	Oral/Enteral Syringes
Common/Usual Name	Gastrointestinal tubes and accessories
Classification Reference	21 CFR 876.5980
Classification	Class II
Appropriate Classification Panel	Gastroenterology / Urology
Product Code	FPD
Predicate Devices	Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944) Respironics, Inc. Enteral Only Extension Set (K082654)

Intended Use/Indications for Use

The Oral/Enteral Syringes is intended for the delivery of liquid medication, formula, and breast milk.

Patient Population/Environment of Use

The patient population is neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral/Enteral Only Syringes is disposable and for single patient use only.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00014

Substantial Equivalence

This traditional 510(k) submittal demonstrates that the Oral/Enteral Syringes are substantially equivalent to the Respironics, Inc. Enteral Only Extension Set (K082654) and the Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944).

Design verification tests were performed on the Oral/Enteral Syringes as a result of the risk analysis and product requirements. The following tests were conducted:

- Volume Measurement Accuracy Testing
- Enteral Feeding Extension Set Interface Testing
- Size and Material Inspection
- Biocompatibility Testing
- Sterility Testing
- Reliability Inspection
- Labeling Inspection
- Environmental Operating Testing
- Storage Testing
- ISTA Testing

Testing Results demonstrated that the Oral/Enteral Syringes meet the required acceptance criteria. Children's Medical Ventures has determined that the Oral/Enteral Syringes are substantially equivalent to the predicate devices.

Device Description

The Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk. The syringes incorporate safety connectors that mate with the Respironics Enteral Only Extension Set, but will not mate with Luer lock or Luer slip fittings. The safety connectors prevent inadvertent connection of the enteral system to an IV system or an IV system to the enteral system. The Oral/Enteral Syringe barrels, plungers and end caps are comprised of Polypropylene, and the pistons are comprised of Silicone.

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00021

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name D Jeffrey Cooper

Subject: 510(k) Number K100099151

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 N, 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.)			✓

Records processed under FOIA Request # 2016-1066; 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
21 CFR 876.5980	II	FPD

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Carolyn Y Neuland (Branch Chief) GRDB (Branch Code) 5/27/10 (Date)

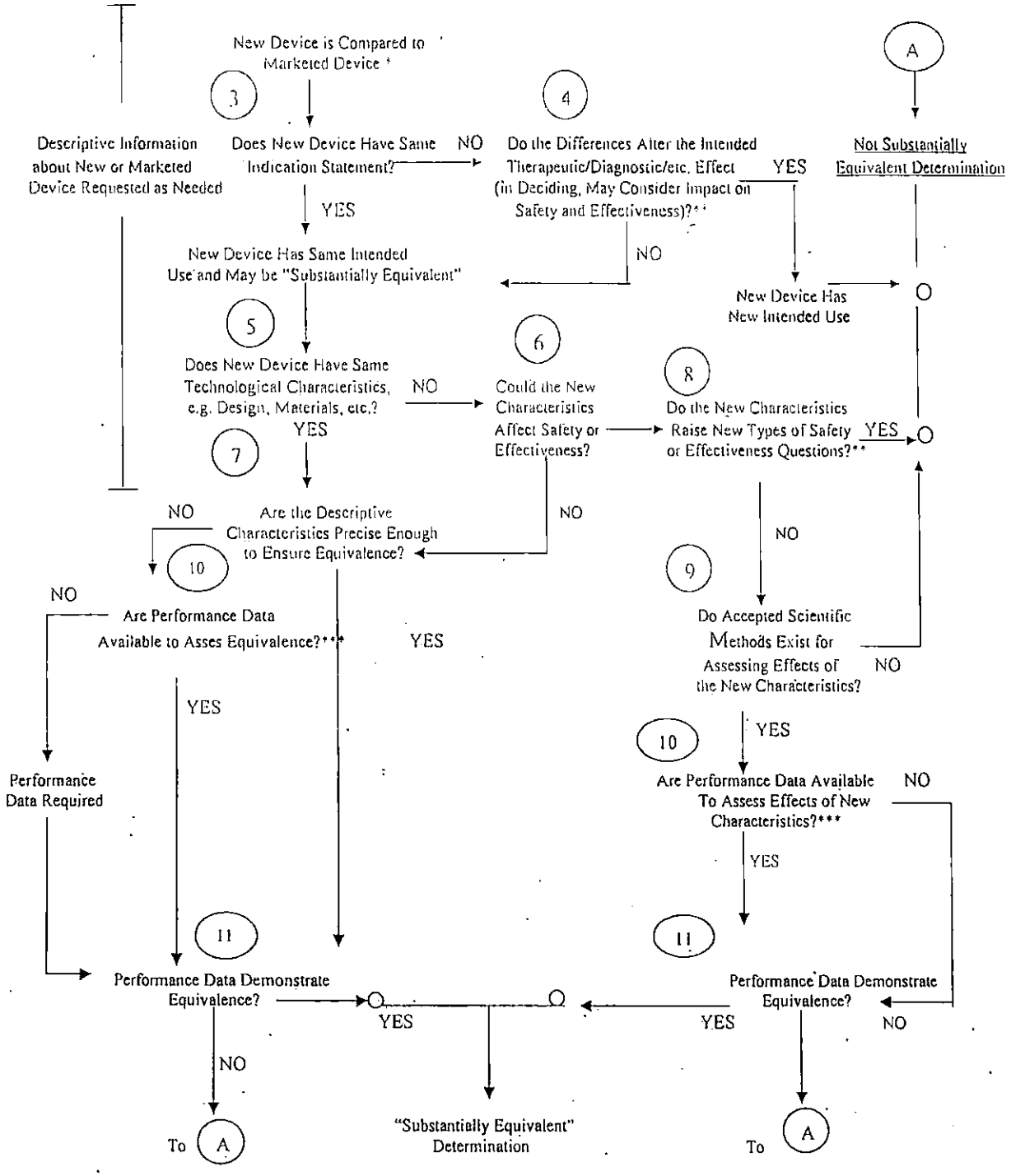
Final Review: _____ (Division Director) _____ (Date)

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00023

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 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00024

MEMORANDUM
Office of Device Evaluation
DRARD/GRDB

Subject: K100099-S1

Date: May 26, 2010

Device: Phillips Children's Medical Ventures, LLC

Company: Library Medical

To: Carolyn Neuland, PhD
Branch Chief

From: Jeffrey Cooper, M.S., D.V.M.
GRDB Veterinary Medical Officer

This is a third party reviewed pediatric enteral feeding syringe.

On the original submission I had found that (b)(4) Deficiencies [redacted]

This supplement provides responses to those two deficiencies. (b)(4) Deficiencies [redacted]. This is adequate.

(b)(4) Deficiencies [redacted]

My concern is that (b)(4) Deficiencies [redacted]

I spoke to Mark Job, the 3rd party reviewer. He will request more information [redacted] told him that this submission will be placed on telephone hold.

(b)

Jeffrey Cooper, M.S., D.V.M.

C. Neuland
5/27/10

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00093

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Jeffrey Cooper

Subject: 510(k) Number K060995

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/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.)			

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

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DJA 00094

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: Carolyn Y Neuland (Branch Chief) GRDB (Branch Code) 1/22/2010 (Date)

Final Review: _____ (Division Director) _____ (Date)

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

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DJA 00095

Cooper, Jeffrey (CDRH)

CJN 1/22/10

From: Cooper, Jeffrey (CDRH)
Sent: Friday, January 22, 2010 4:38 PM
To: 'mark@markjob.com'
Subject: K100099

Mark Job-

I have looked at your review of K100099 and I have a few questions. (b)(4) Deficiencies

[redacted]

Thanks,

Jeffrey Cooper. M.S., D.V.M.
Veterinary Medical Officer
Center for Devices & Radiological Health (CDRH)
Office of Device Evaluation (ODE)
Division of Reproductive, Abdominal and Radiological Devices (DRARD)
Gastroenterology and Renal Devices Branch (GRDB)
WO66 G228
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
(301) 796-6517
jeffrey.cooper@fda.hhs.gov

On Friday at 7:15Pm I left a voice mail for Mr MarkJob, Third party offered reviewer, alerting him of Dr Coopers email above and telling him That The 510(k) would be placed on Telephone Hold until The above issues are responded to in writing.

C. Haugland
Chief, GRDB
1/22/2010.

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

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DJA 00096

THIRD PARTY REVIEW CHECKLIST

1. Is this 510(k) eligible for third party review, i.e.:		
a. Is the device on the list of eligible devices?* P/ct	(Yes)	No
b. Can a determination of substantial equivalence be made without clinical data?	(Yes)	No
c. Are you aware of the 510(k) holder being the subject of an Integrity Investigation?	Yes	(No)

IF THE ANSWER IS "NO" TO A or B above, or "YES" to C above, PLEASE BRING THE SUBMISSION TO POS IMMEDIATELY.

Are the following elements included in the submission:

2. A cover letter signed by the third party's official correspondent clearly identifying:		
a. The purpose of the submission	(Yes)	No
b. The name and address of the third party	(Yes)	No
c. The name and address of the 510(k) holder	(Yes)	No
d. The name of the device (trade name, common or usual name, and FDA classification name)	(Yes)	No
e. The third party's recommendation with respect to the substantial equivalence of the device	(Yes)	No
f. The date the third party first received the 510(k) from the 510(k) holder	(Yes)	No
3. A letter signed by the 510(k) holder authorizing the third party to submit the 510(k) on its behalf and to discuss its contents with FDA.	(Yes)	No
4. The complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions.	(Yes)	No

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

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5. A complete review of the 510(k), signed by all personnel who conducted the third party review and by an individual within the third party responsible for supervising third party reviews, with a recommendation concerning the substantial equivalence of the device.	(Yes)	No

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

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DJA 00098

6. A certification that:		
a. The third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA	Yes	No
b. Statements made in the third party's review are true and accurate to the best knowledge of the third party	Yes	No
c. The third party's review is based on the 510(k) that it is submitting with the review	Yes	No
d. The third party understands that the submission to the government of false information is prohibited	Yes	No

7. Are the following forms included in the submission as discussed in the Center's guidance document entitled Third Party Review-An Instruction Manual for Conducting Reviews of Premarket Notifications:		
a. Third Party Premarket Notification (510(k)) Checklist for Acceptance Decision (Parts I and II)	Yes	No
b. Record of Deficiencies, if applicable (attachment 1a)	Yes	No
c. Indications for Use Form	Yes	No
d. 510(k) Summary or Statement (attachment 1c)	Yes	No
e. 510(k) Truthful and Accurate Statement (attachment 1d)	Yes	No
f. Third Party "Substantial Equivalence" (SE) Decision Making Documentation (attachment 2)	Yes	No

IF ANY OF THE ABOVE INFORMATION IS NOT INCLUDED WITH THE THIRD PARTY'S SUBMISSION OR IS NOT ADEQUATE, CONTACT THE THIRD PARTY AND ATTEMPT TO RESOLVE THE DEFICIENCY. PLEASE INCLUDE A MEMORANDUM TO THE RECORD OF THE TELEPHONE CALL. WHEN THE INFORMATION IS RECEIVED PLEASE REVISE THIS CHECKLIST OR COMPLETE A NEW ONE.

1/27/10

COMMENTS: _____

_____

_____

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

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DJA 00099

*If the third party incorrectly classified the device and it is not a device type eligible for third party review please bring to POS.

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

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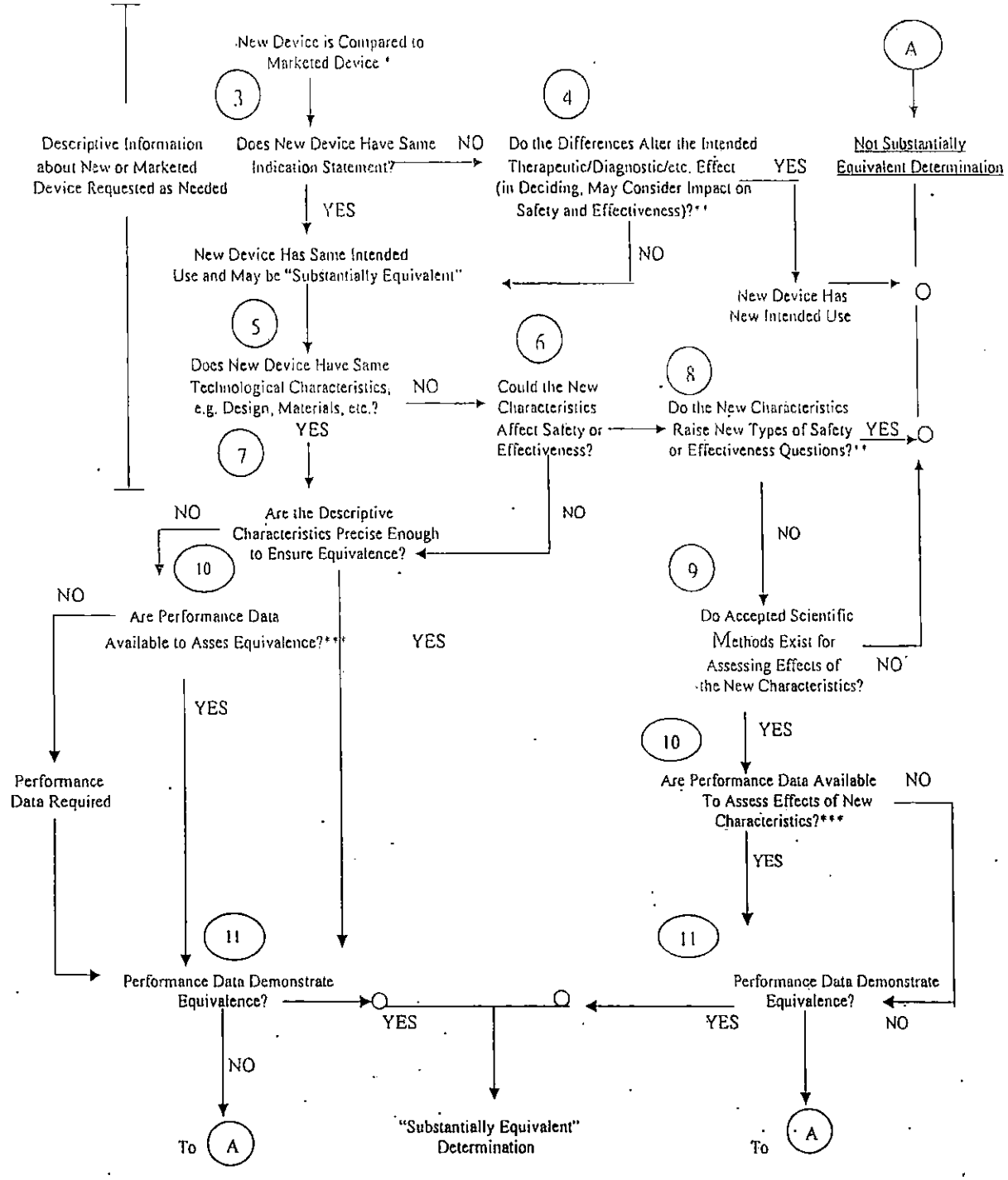
DJA 00100

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 may be 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 301-796-8118

DJA 00025

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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

May 12, 2010

PHILIPS CHILDREN'S MEDICAL VENTURES
c/o REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET, NW
BUFFALO, MINNESOTA 55313
UNITED STATES
ATTN: MARK JOB

510k Number: K100099
Product: ORAL/ENTERAL SYRINGES

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 301-796-8118

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DJA 00026

K100099 /31

Date: May 11, 2010

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

FDA CDRH DMC
MAY 12 2010
Received

K13

RE: Premarket Notification 510(k):

K100099
PHILIPS CHILDREN'S MEDICAL VENTURES
ORAL/ENTERAL SYRINGES

To Whom It May Concern:

Enclosed in duplicate is the following information:

As requested by email from Jeffery Cooper dated January 22, 2010, requesting additional information for this submission. Additional information has been supplied by the sponsor and has been reviewed according to the request and found to meet all requirements. This additional information includes a revised reviewer memorandum (see attached). This additional information and the original submission does not raise any new questions related to the safety or effectiveness of the subject device. A Substantially Equivalence decision is recommended.

If you should have any questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

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

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DJA 00027

REVISED
Third Party Review
Reviewer Memorandum

Third Party Organization: Regulatory Technology Services LLC

Primary Reviewer: Mark Job

Signature: Date: May 11, 2010

Print Name: Mark Job Title: Reviewer

510(k) Applicant's Name: **Philips Children's Medical Ventures**

Device Name: **Oral/Enteral Syringes**

Contact Person: Lisa Casavant

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

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00028

I. Purpose and Submission Summary:

The 510(k) holder (**Children's Medical Ventures**) would like to introduce **Oral/Enteral Syringes** into interstate commerce. During the review deficiencies were found which required additional information from the sponsor. The sponsor provided a response to all concerned items and all questions are resolved. This submission is very similar to the predicate devices. The submission includes performance testing protocols, purpose, pass / fail criteria, and a summary of the results.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Prescription) Page Number: **TAB 4**	X		
Truthful and Accuracy Statement Page Number: **TAB 6**	X		
510(k) Summary Page Number: **TAB 5**	X		
Standards Form (FDA Form 3654) Page Number: **TAB 9**	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

The Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk. The syringes incorporate safety connectors that mate with the Respironics Enteral Only Extension Set, but will not mate with Luer lock or Luer slip fittings. The safety connectors prevent inadvertent connection of the enteral system to an IV system or an IV system to the enteral system. The

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DJA 00029

submission states the Oral/Enteral Syringes are intended to be used in the hospital or home environment, by trained caregivers only.

Material Description

The Oral/Enteral Syringes are comprised of four parts; the barrel, plunger, the piston, and an end cap. The material used to manufacture each part is found in the table below.

Materials used to manufacture the Oral/Enteral Syringes

Part	Material
Barrel	Polypropylene (b)(4)
Plunger	Polypropylene
Piston stopper (attaches to end of plunger to create seal)	(b)(4) Silicone (b)(4)
End Cap (attached to output port of barrel)	(b)(4)

All materials have been evaluated in accordance with ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. The submission includes the details of the testing and the test results.

The device description is similar to the predicate devices and does not raise any questions related to safety and effectiveness.

IV. Indications for Use

Oral/Enteral Syringes are intended for the delivery of liquid medication, formula, and breast milk.

Patient Population/Environment of Use:

The patient population is neonates and infants. The environments for use are hospital and home environments by trained caregivers only. The Oral/Enteral Syringes are disposable and for single patient use only.

The indications for use form is included in the submission in TAB 4. The device is for prescription use. The intended use is the same as the combination of the predicate devices.

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

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V. Predicate Device Comparison

The submission provides a comparison between the new device the Children's Medical Ventures Oral/Enteral Syringes and the predicate devices the Vygon Nutrisafe 2 System Transparent Syringes cleared under K060944 and the Respironics Enteral Extension Set cleared under K082654. The following is a comparison table which includes a comparison of the indications for use and the device specifications.

	Predicate Device: Respironics Inc. Enteral Only Extension Set (K082654)	**Predicate Device:** Vygon Corp. Nutrisafe 2 System Transparent Syringes (K060944)	**Proposed Device:** ChMV Oral/Enteral Syringes
Intended use	The Enteral Only Extension Set is intended for use as an extension set for nasogastric/ oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors which reduce the risk of accidental connection of an I.V. system to the enteral system, or the enteral system to an I.V. system.	For nasogastric/oralgastric enteral feeding.	Oral/Enteral Syringe is Intended for delivery of liquid medication, formula, and breast milk.
Environment of Use	Hospital/institutional environment	Hospital, home, or environments where placement of a feeding tube is required	Hospital and home environment by trained caregivers only.
Patient Population	Pediatric and adult use	Neonates and Infants	Neonates and Infants
Product Code (Regulatory Description)	KNT	FPD	FPD
Patient Usage Type	Single use	Single use	Single use
Device Usage Type	Disposable	Disposable	Disposable
Design	Connects to enteral syringes and enteral extension sets	Connects to enteral feeding tubes or enteral extension sets	Connects to enteral feeding tubes or enteral extension sets
Non-IV Compatible Connector	Yes	Yes	Yes
Material	(b)[redacted]	Unknown	Barrel & Plunger: Polypropylene (b)(4)[redacted]; Piston: (b)(4)[redacted] Silicone (b)(4)[redacted] End Cap: (b)(4)[redacted]
Sizes	60" (152 cm) and 36" (91 cm)	1, 2, 5, 10, 20, and 60 ml	1, 3, 5, 10, 20, 30, and 60 ml
Sterility Condition	Sterile	Sterile	Sterile
Packaging Material	(b)(4)[redacted] pouch	unknown	(b)(4)[redacted] (b)(4)[redacted]

The table above demonstrates the new device has the same intended use, similar

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

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physical properties, the same performance characteristics, and similar materials as the predicate devices. This comparison does not raise new questions of safety and effectiveness.

VI. Labeling

The labeling includes all the appropriate cautions and warnings to the user. The labeling is contained within the TAB 13 of the submission. The labeling includes all instructions and warnings related to the use of the subject device. The labeling includes samples of each version (size) included in this submission. The labeling is similar to the labeling of the predicate device which was not provided but was extracted from the website and included as part of this document with the clearance letter from the FDA website. No new claims are made which would raise questions of safety and effectiveness.

VII. Sterilization/Shelf Life/Reuse

The sterilization information is included in section 14 of the submission. The sterilization validation is declared to be validated according to the (b)(4) Risk (b)(4) of the standard. This method will be sufficient to ensure product is sterile. The devices will be sterilized using (b)(4) . The validation of the sterilization process will demonstrate the product has a sterility assurance level (SAL) of 1(b) This level of is adequate for device to be considered sterile. The sterilization information included in TAB 14 includes information related to the evaluation of the residuals (page 1). All information presented indicates the new device meets specifications. The sterilization method use for the new device though not clearly stated in the submission is the same as the predicate devices. The package information is stated to be identical to the device (a syringe) cleared under K042500. The sponsor (see additional information dated May 7, 2010) has included rationale and justification for not including test results after real time aging because the subject device is identical to the device cleared under K042500 in manufacturing, material, and packaging design. The differences are noted to be the tip cover which is considered to not be an integral component to fit, form, or function of the subject device. No new questions of safety and effectiveness are raised.

VIII. Biocompatibility

The device has been tested to demonstrate conformance to the appropriate parts of ISO 10993 to ensure compatibility to the materials. The following table provides a reference between each component and material and the type of contact to the patient and / or fluid.

Oral/Enteral Syringe Component	Type of Patient Contact	Contact with feeding solution?	Material
Barrel	Indirect	Yes	Polypropylene (b)(4)

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

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Plunger	Indirect	No	Polypropylene (b)(4)
Piston (attaches to end of plunger to create seal)	Indirect	Yes	(b)(4) Silicone (b)(4)
Lubricant	Indirect	Yes	(b)(4)
End Cap (attached to output port of barrel)	Indirect	No	(b)(4)

The following table presents the results of the tests performed for each component of the device.

Component	Material	Testing or Analysis performed
Barrel	The barrel is polypropylene (b)(4) Color: *1 ml-* Orange (b)(4) *5 ml–60 ml-* Transparency	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
Piston	The piston is (b)(4) Silicone (b)(4) (b) Color: Black	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
Plunger	The plunger is polypropylene (b)(4) Color: *1 ml-* White *5 ml-60 ml-* Orange (b)(4)	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
Lubricant	The syringe lubricant is (b)(4) (b)(4)	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}
End Cap	The end cap is (b)(4) Color: Orange (b)(4)	ISO-10993-1, Category A (< 24 hrs).[1] {tested for Cytotoxicity (ISO 10993-5) and Irritation & Sensitization (ISO 10993-10)}

The table above provides a summary of the actual test reports provided in the submission and the additional information dated January 7, 2010. The test reports demonstrate for short duration (<24 hours) contact of intact mucosal membrane the tests are appropriate and meet the requirement for this type of contact in accordance with Blue book Memo G95-1. No new questions related to the safety are raised.

IX. Software

This device does not employ software.

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

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DJA 00033

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

This is not electrically powered.

XI. Performance Testing – Bench

This section was updated as a result of additional information received from the sponsor on May 7, 2010. The addition information includes bench testing performed to verify the design performance of the Oral/Enteral Syringes. The testing was performed on final finished sterilized devices. The following table extracted from the submission provides a summary of the tests performed.

PRD (reference 1) Requirement	Verification Test Procedure (reference 4)	Test Result
(b)(4)		

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

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DJA 00034

PRD (reference 1) Requirement	Verification Test Procedure (reference 4)	Test Result
(b)(4)		

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

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DJA 000035

PRD (reference 1) Requirement	Verification Test Procedure (reference 4)	Test Result
(b)(4)		

The submission states the test results which are indicated as "Pass" are stated to meet the intended design requirements after sterilization on final configuration finished devices. The testing results demonstrate the Oral/Enteral Syringes meet the design requirements. The performance testing included in the submission also includes side by side testing with the predicate device. The Performance Test data is presented in TAB 18 and the additional information dated May 7, 2010. Scientifically the test results demonstrate the safety and effectiveness of the device. No new concerns related to performance of the new device are raised.

XII. Performance Testing – Animal

This submission does not include animal clinical testing or data.

XIII. Performance Testing – Clinical

This submission does not include human clinical testing or data

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

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XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		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?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	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?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: **SE**

Note: Document the decision path by marking the arrows followed on the FDA flowchart.

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:

The submission includes the descriptive characteristics but the (b)(4) [redacted]

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 301-796-8118

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00037

7. Explain why existing scientific methods cannot be used:

8. Explain what performance data is needed:

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

As the reviewer of this submission I have reviewed the instructions for use, the submitter's description of the device and compared this information against the information concerning the predicate devices that was provided by the submitter. The specifications for the predicate device and the new device have been compared. They are nearly identical. The comparison differences described in the comparison table are similar between the devices. The submission states the patient contact materials are similar to the predicate devices and the test results have been included in the submission in TAB 18. The sterilization and packaging are not indicated as being different than the predicates but they are presented and meet the prescribed FDA requirements. The submission includes performance testing which demonstrating in side by side comparisons between the new device and the predicate device the new device employs similar performance characteristics. The labeling included in the submission was reviewed. There are no new questions of safety and effectiveness raised during this review.

Based upon the above summary, a substantially equivalent decision is recommended.

XV. Deficiencies

All deficiencies presented to the sponsor are included in the documentation of the review and are included in this submission. The sponsor has addressed all deficiencies.

XVI. Contact History

All correspondence is included in the submission.

XVII. Recommendation

Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: FPD

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

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DJA 00038

May 7, 2010

Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

ATTN: Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

RE: Response to RAI, 510(k) Notification, Children's Medical Ventures' Oral/Enteral Syringes

Dear Mark:

Children's Medical Ventures (ChMV) hereby submits this response to your request for additional information provided in the E-mail dated January 22, 2010. If you require additional information, please do not hesitate to contact me by phone or E-mail.

Sincerely,

Lisa Casavant

Primary Contact:
Name: Lisa Casavant
Title: Regulatory Affairs Consultant
Phone: 724-244-2624
Fax: 412-380-8850
Email: Lisa.Casavant@philips.com

Secondary Contact:
Name: Matthew Young
Title: Manager, Quality Assurance and Regulatory Affairs
Phone: 724-387-4012
Fax: 412-380-8850
Phone: Matthew.Young@phillips.com

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

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DJA 000039

(b)(4) Deficiencies

[redacted]

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

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DJA 000040

DESIGN V&V REPORT SPECIFICATION

Oral/Enteral syringe

ER#: (b)(4)

Version#: (b)(4)

Prepared by: (b)(6)

Respironics, Inc.
Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

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RESPIRONICS®

Revision History

Version Number	Date	Description of Changes	Contributors
(b)(4)	11/9/09	(b)(4), (b)(6)	
	11/10/09		
	12/2/09		
	5/6/10		
	5/10/10		

Contributors

- Design V&V – (b)(6)
- Engineering – (b)(6)
- Design Quality Engineering – (b)(6)
- Risk Management – (b)(6)
- Reliability Management – (b)(6)
- Design Lab Management – (b)(6)
- Regulatory Affairs – Lisa Casavant (LC)
- Clinical Affairs
- Design Engineering
- Operations Equipment Engineering
- Operations Process Validation
- Operations Supplier Quality Assurance – (b)(6)
- Project Manager - (b)(6)
- Product Manager – (b)(6)

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

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DJA 00042

(b)(4) Design V&V Report Specification

(b)(4) Design V&V Report Specification

(b)(4) Design V&V Report Specification

(b)(4) Design V&V Report Specification

(b)(4) Design V&V Report Specification

Records processed under FOIA Request # 2016-1066; Released by CDRH on 06-06-2016

DJA 00048

2/2010 Original Results

Oral/Enteral syringe

TEST PROCEDURE SPECIFICATION

Oral/Enteral syringe

ER#: (b)(4)

Version#: (b)(4)

Prepared by: (b)(6)

Respironics, Inc.
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DJA 00049

Revision History

Version Number	Date	Description of Changes	Contributors
(b)	9/29/09	(b)(4)	(b)(6)
(b)	10/8/09		

Contributors

- Design V&V – (b)(6)
- Engineering – (b)(6)
- Design Quality Engineering – (b)(6)
- Risk Management – (b)(6)
- Reliability Management
- Design Lab Management
- Regulatory Affairs – Compliance Testing and Labeling
- Clinical Affairs
- Design Engineering
- Operations Equipment Engineering
- Operations Process Validation
- Operations Supplier Quality Assurance
- Project Manager - (b)(6)
- Product Manager – (b)(6)

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(b)(4) Test Procedure Specification

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DJA 000076

(b)(4) Testing

ER#: (b)(4)

Version#: (b)(4)

Prepared by: (b)(6)

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191 Wyngate Drive
Monroeville, PA 15146

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Questions? Contact FDA/CDR 796-8118

(b)(4) Testing

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(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Third Party Information

DJA 00015

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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

June 04, 2010

PHILIPS CHILDREN'S MEDICAL VENTURES
c/o REGULATORY TECHNOLOGY SERVICES, LLC
1394 25TH STREET, NW
BUFFALO, MINNESOTA 55313
UNITED STATES
ATTN: MARK JOB

510k Number: K100099

Product: ORAL/ENTERAL SYRINGES

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 301-796-8118

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K100099/8002

DJA 00016

Date: June 3, 2010

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

FDA CDRH DMC
JUN 04 2010
Received

RE: Premarket Notification 510(k):

K100099
PHILIPS CHILDREN'S MEDICAL VENTURES
ORAL/ENTERAL SYRINGES

To Whom It May Concern:

Enclosed in duplicate is the following information:

As requested during a telephone conversation with Jeffery Cooper on May 27, 2010, requesting additional information for this submission. Additional information has been supplied by the sponsor and has been reviewed according to the request and found to meet all requirements. This additional information does not raise any new questions related to the safety or effectiveness of the subject device. A Substantially Equivalence decision is recommended.

If you should have any questions regarding this submission please contact me at 763 682 4139 or fax 763 682 4420. Please fax any correspondence regarding this submission to Regulatory Technology Services LLC.

Sincerely,

Mark Job
Responsible Third Party Official

F-10

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

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DJA 00017

June 2, 2010

Children's Medical Ventures
191 Wyngate Drive
Monroeville, PA 15146

ATTN: Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

RE: Response to RAI, 510(k) Notification # K100099, Children's Medical Ventures' Oral/Enteral Syringes

Dear Mark:

Children's Medical Ventures (ChMV) hereby submits this response to your request for additional information provided by phone on May 27, 2010. If you require additional information, please do not hesitate to contact me by phone or E-mail.

Sincerely,

Lisa Casavant

Primary Contact:
Name: Lisa Casavant
Title: Regulatory Affairs Consultant
Phone: 724-244-2624
Fax: 412-380-8850
Email: Lisa.Casavant@philips.com

Secondary Contact:
Name: Matthew Young
Title: Manager, Quality Assurance and Regulatory Affairs
Phone: 724-387-4012
Fax: 412-380-8850
Phone: Matthew.Young@phillips.com

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

(b)(4) Deficiencies