



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K120562 - 590 pages
COMPANY: RESPIRONICS, INC. (RESPIRONICS)
PRODUCT: VENTILATOR, NON-CONTINUOUS (RESPIRATOR) (BZD)
SUMMARY: Product: PERFORMAX PEDIATRIC EE TOTAL FACE MASK

DATE REQUESTED: Apr 25, 2016

DATE PRINTED: Apr 25, 2016

Note: Printed



TAB 5

JUL 17 2012

510(K) SUMMARY

K 12 0562

Date of Submission	21 February 2012
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-4146 (724) 387-3999 (fax)
Official Contact	Michelle Brinker Regulatory Affairs Manager, Patient Interface
Proprietary Name	PerforMax Pediatric EE Total Face Mask
Common/Usual Name	Face Mask
Classification Name / Product Code	BZD – Ventilator, Non-Continuous (Respirator)
Predicate Device(s)	Respironics PerforMax Youth EE Total Face Mask (K092043) Respironics Small Child Profile Lite Nasal Mask (K093416)

Device Description

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. It provides a seal such that positive pressure from the positive pressure source is directed into the patient's nose and mouth. It is held in place with an adjustable bonnet headgear. It may be cleaned by the professional in the hospital/institutional environment through a thermal high-level disinfection process or a chemical high-level disinfection process for multi-patient use.

The PerforMax Pediatric EE Total Face Mask consists of a faceplate with a bonded silicone seal for the face and an elbow with an integral entrainment valve. The mask features an interchangeable elbow hub which accepts an EE Leak 1 and EE Leak 2 elbow. The EE Leak 2 elbow includes built-in exhalation, an entrainment valve, a flexible tube, and a 22 mm connection. The EE Leak 1 elbow includes an entrainment valve and a 22 mm connection. The 22 mm elbow is used to connect a conventional air delivery hose between the mask and the positive airway pressure source. The bonnet headgear is

connected to the mask through slots in the upper part of the frame and clips that attach to the lower part of the frame. The mask is designed in such a way that it can be easily disassembled for disinfection or to replace several of the mask components, such as the headgear and elbow.

Intended Use

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Summary of Technological Characteristics of Device Compared to the Predicate Devices

The PerforMax Pediatric EE Total Face Mask has the following similarities in the technological characteristics to the previously cleared devices (Respironics PerforMax Youth EE Total Face Mask, K092043, and Respironics Small Child Profile Lite Nasal Mask, K093416):

1. Same intended use
2. Same operating principle
3. Same technology
4. Similar device design
5. Similar physical properties
6. Similar materials used
7. Same scientific concepts that form the basis for the device

The PerforMax Pediatric EE Total Face Mask has the following differences in the technological characteristics to the previously cleared devices (Respironics PerforMax Youth EE Total Face Mask, K092043, and Respironics Small Child Profile Lite Nasal Mask, K093416):

1. Faceplate and cushion have been reduced in size.
2. Elbow modified
3. Operating pressure range has been modified.
4. Addition of inspiratory and expiratory resistance performance specification.
5. Mask leak specifications has been modified.
6. The elbow body, elbow hub, and headgear materials have been modified.

Summary of the Non-Clinical Test Submitted, Referenced or Relied on in the 510(k)

To demonstrate performance and functionality was unaffected as a result of these changes, extensive performance testing was completed. Testing was performed pre and post hospital/institutional cleaning and disinfection treatments. Additionally, the mask was tested for high level disinfection in accordance with AAMI TIR No. 12-2004, AAMI TIR 30-2003, ASTM E1837-96 (2007), and the “Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants” – FDA CDRH, January 3, 2000. All patient contacting or gas path materials used in the mask have been previously cleared by the FDA or evaluated in accordance with the guidance provided by ISO 10993-1.

Results from this testing demonstrate that the PerforMax Pediatric EE Total Face Mask meets its performance specifications, raises no new issues of safety or effectiveness, and is substantially equivalent to the identified device predicates.

Clinical Data

Use of face masks with CPAP or bi-level therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the PerforMax Pediatric EE Total Face Mask, as was the case with the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Michelle Brinker
Regulatory Affairs Manager, Patient Interface
Respiroics, Incorporated
Sleep and Home Respiratory Group
365 Plum Industrial Court
Pittsburg, Pennsylvania 15239

JUL 17 2012

Re: K120562
Trade/Device Name: PerforMax Pediatric EE Total Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 9, 2012
Received: July 10, 2012

Dear Ms. Brinker:

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 adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120562

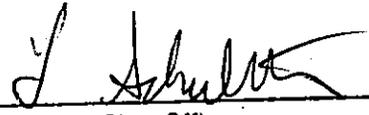
Device Name: PerforMax Pediatric EE Total Face Mask

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120562



DEPARTMENT OF HEALTH & HUMAN SERVICES

K120562/OR.V1

Public Health Service

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

March 29, 2012

RESPIRONICS, INC.
SLEEP AND HOME RESPIRATORY GROUP
365 PLUM INDUSTRIAL COURT
PITTSBURGH, PENNSYLVANIA 15239
ATTN: MICHELLE BRINKER

510k Number: K120562

Product: PERFORMAX PEDIATRIC EE TOTAL F

On Hold As of 3/27/2012

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/MedicalDeviceProvisionsofFDAModer nizationAct/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.

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

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Thursday, March 29, 2012 8:10 AM
To: 'michelle.brinker@philips.com'
Subject: Hold Letter
Attachments: image002.png

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

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

March 29, 2012

BRINKER
MICHELLE

RESPIRONICS, INC.
 SLEEP AND HOME RESPIRATORY GROUP
 365 PLUM INDUSTRIAL COURT
 PITTSBURGH, PENNSYLVANIA 15239
 ATTN: MICHELLE BRINKER

510k Number: K120562

Product: PERFORMAX PEDIATRIC EE TOTAL F

On Hold As of 3/27/2012

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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.

3/29/2012

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Sincerely yours,

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

Grayson, Giovanna *

From: Microsoft Outlook
To: 'michelle.brinker@philips.com'
Sent: Thursday, March 29, 2012 8:10 AM
Subject: Relayed: Hold Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'michelle.brinker@philips.com'

Subject: Hold Letter

Sent by Microsoft Exchange Server 2007



COVER SHEET MEMORANDUM

From: Reviewer Name LEE
Subject: 510(k) Number K120562
To: The Record

Please list CTS decision code _____

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NM NSE requires PMA
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, 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)? For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			

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 \geq 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC.

Regulation Number

Class*

Product Code

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

Additional Product Codes: _____

Review: _____

L. Schuller
(Branch Chief)

ARDB
(Branch Code)

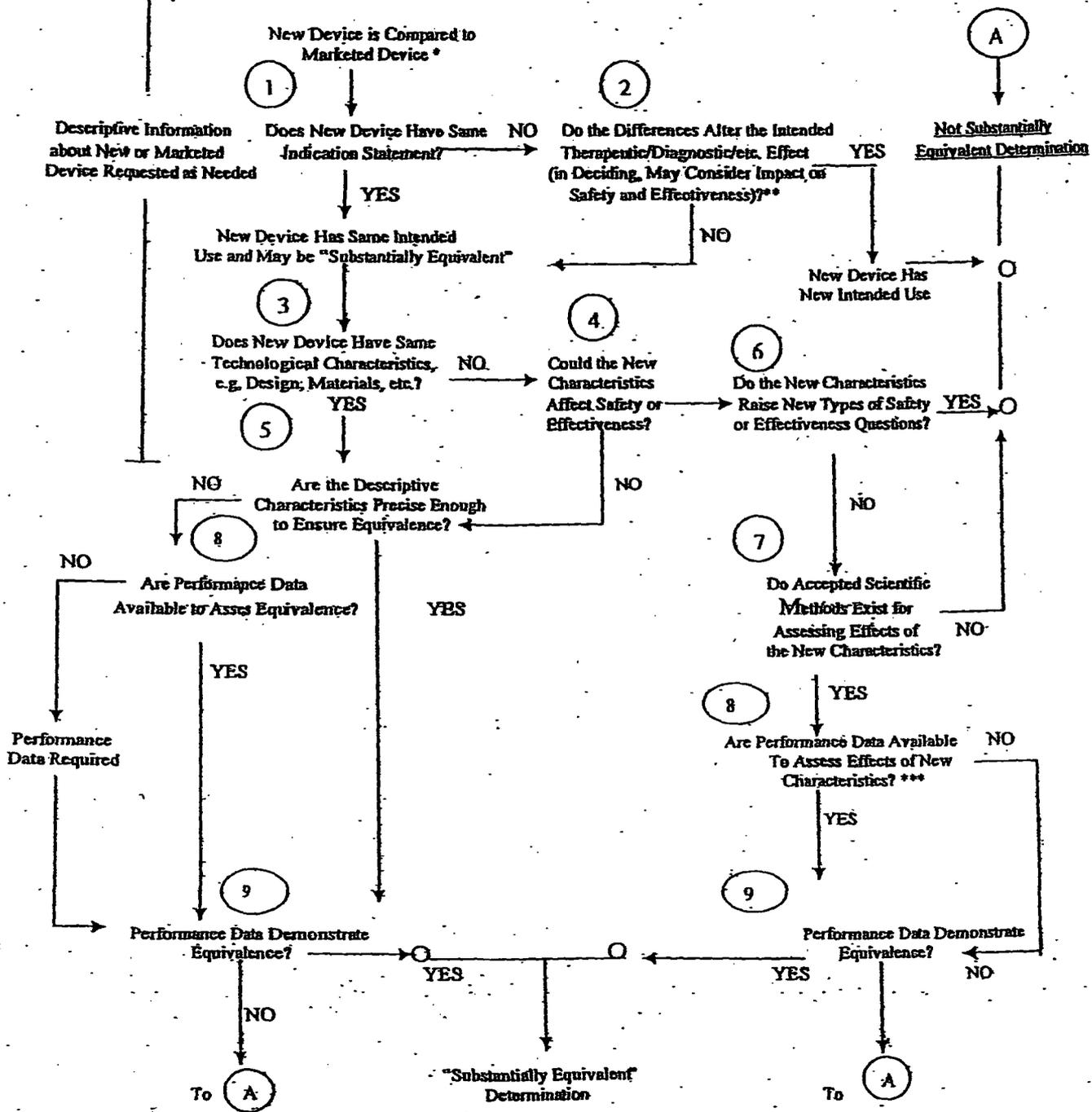
3/27/12
(Date)

Final Review: _____

(Division Director)

(Date)

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.



Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K120562

Date: March 27, 2012
To: The Record
From: James Lee PhD
510(k) Holder: RESPIRONICS INC
Device Name: PerforMax Pediatric EE Total Face Mask
Contact: Michelle Brinker
Phone: (724) 387-4146
Fax: (724) 387-3999
Email: michelle.brinker@philips.com

Office:
Division: DAGID/ARDB

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the Respironics PerforMax Pediatric EE Total Face Mask into interstate commerce. The PerforMax Pediatric EE Total Face Mask is a modification in design to the Respironics PerforMax Youth EE Total Face Mask (previously cleared under K092043) and Respironics Small Child Profile Lite Nasal Mask (previously cleared under K093416). The modifications consist of the following:

1. Updated environment to restrict to hospital/institutional use only
2. Reduced size of the faceplate and cushion
3. Modified elbow
4. Modified the mask operating pressure range, replaced unintentional leak specification with total mask leak specification, and added inspiratory and expiratory resistance specification
5. Material changes for the elbow hub, elbow body, and headgear

The modified device is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The PerforMax Pediatric EE Total Face Mask is for patients 1 year or older (> 7 kg). The mask is for multi-patient use in the hospital / institutional environment only.

II. Administrative Requirements

		Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	Provided in Section 4	X		
Truthful and Accuracy Statement	Provided in Section 6p	X		
510(k) Summary or 510(k) Statement	Provided in Section 5	X		
Standards Form				

510(k) Summary

The sponsor has provided its 510(k) Summary in Section 5.

Required Elements for 510(k) Summary (21 CFR 807.92)		
	Clearly labeled "510(k) Summary"	yes
	Submitter's name, address, phone #, a contact person	yes
	Date the summary was prepared	yes
	The name of the device/trade name/common name/classification name	yes
	An identification of the legally marketed predicate	yes
	Description of the subject device	yes
	Statement of intended use	yes
Technological characters	if same, a summary of comparison of technological characters	yes
	If different, a summary of how do they compare to the predicate	
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	yes
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> - Description upon whom the device was tested, - Data obtained from the tests and especially: <ul style="list-style-type: none"> ▪ Adverse events and complications ▪ Other information for SE determination 	
	Conclusion that data demonstrate SE	
Required Elements for 510(k) Statement (21 CFR 807.93)		N/A
	Signed verbatim statement	

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?			

The Performax Pediatric EE Total Face Mask expands upon the existing Respiration Performax product line, which currently includes a size cleared for patients 7 years and older (> 18.2 kg).

The Performax Pediatric EE Total Face Mask consists of a (b)(4) faceplate, a silicone cushion that seals along the perimeter of the face, an elbow with an integral entrainment valve, and an

elbow hub that retains the elbow. A pressure-pick off port is located on the elbow body. The mask is secured to the head with a bonnet style headgear.

The PerforMax elbow hub allows the medical professional to use the mask with either an Entrainment Elbow (EE) Leak 2 or an Entrainment Elbow (EE) Leak 1. The EE Elbow is a simple press fit assembly into the hub of the mask.

(b)(4)

(b)(4)

The EE Leak 2 elbow has a 6" fixed 15 mm to 22 mm flexible extension tube attached. There is a 22 mm swivel connector at the end of the tubing to attach to standard 22 mm tubing used with CPAP and bi-level systems. The EE Leak 1 elbow connects directly to standard 22 mm tubing used with CPAP and bi-level systems (see Figure 3). The EE Leak 1 elbow does not include an extension tube or swivel. The PerforMax Pediatric EE Total Face Mask is available in two sizes, XS and XXS.

IV. Indications for Use

Indications for Use as provided in Section 4 of the original submission:

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bilevel system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Prescription Use has been indicated.

Predicate Indications for Use:

PerforMax Youth EE Total Face Mask (K092043) –

The Respironics BiPAP Synchrony 2 is intended to provide non-invasive ventilation for pediatric patients 7 years or older(> 40 lbs) or adult patients (> 66 lbs) with respiratory insufficiency or obstructive sleep apnea, in the hospital or home.

Small Child Profile Lite Nasal Mask (K093416) –

The Respironics Trilogy200 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy200 is intended for pediatric through adult patients weighing at least 5 kg (11 lbs.).

The device is intended to be used in home, institution/hospital, and portable applications such as wheelchairs and gurneys, and may be used for both invasive and non-invasive ventilation

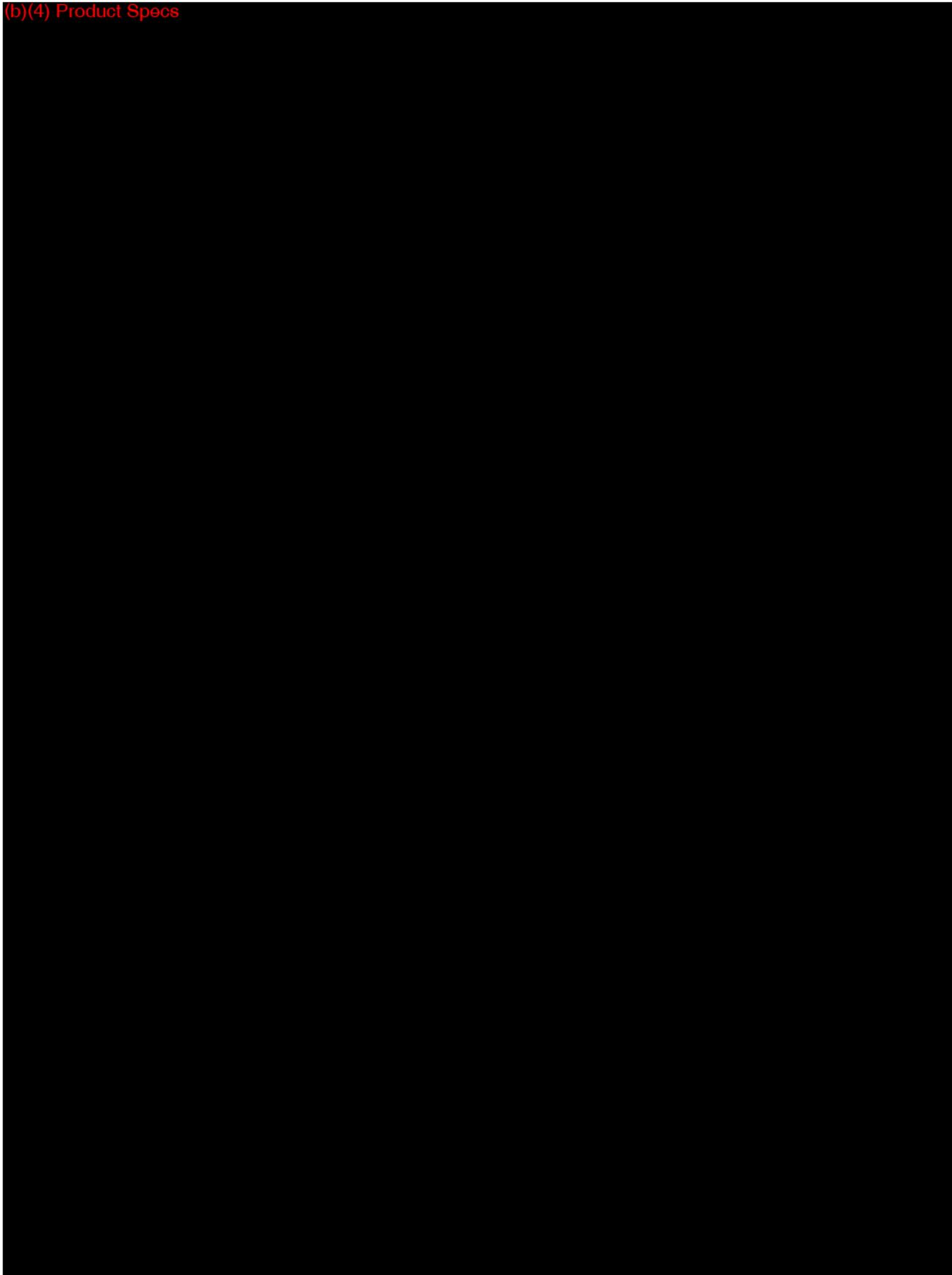
V. Predicate Device Comparison

(b) (4)

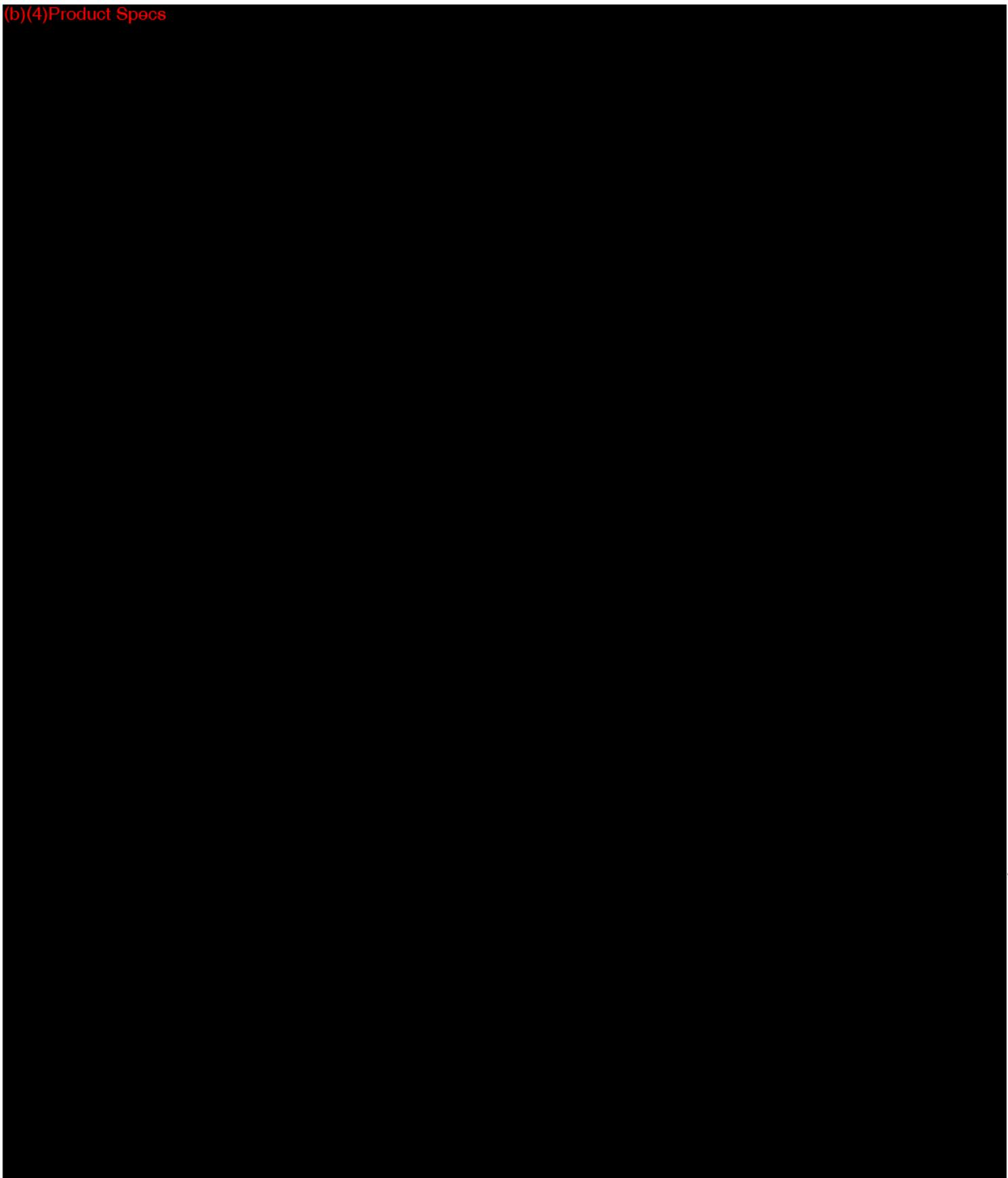
The following table compares the submitted device with the primary and secondary predicates.

	Primary Predicate Device: PerforMax Youth EE Total Face Mask Manufacturer: Respironics, Inc. 510(k) Number: K092043	Secondary Predicate Device: Small Child Profile Lite Nasal Mask Manufacturer: Respironics, Inc. 510(k) Number: K093416	Subject Device: PerforMax Pediatric EE Total Face Mask Manufacturer: Respironics, Inc. 510(k) Number: To be determined
Intended Use submitted in labeling	The PerforMax Youth EE Total Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients.	The Small Child Profile Lite Nasal Mask and Softcap are intended to provide an interface when used with CPAP or bi-level therapy.	Similar to K092043 and K093416 PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system.
<i>Patient Population</i>	7 years or older (> 18.2 kg)	1 year or older (> 7 kg)	Unchanged from K093416
<i>Environment of Use of the System</i>	Home or Hospital/institutional	Home or hospital/institutional	Hospital/institutional only
<i>Patient Usage Type</i>	Single Patient use in the home and Multi-patient use in the hospital/institutional environment	Single Patient Use	Unchanged from K092043 in the Hospital/institutional environment
<i>Product Code</i>	MNS	CBK	BZD
<i>Provided Sterile or Non-Sterile</i>	Provided clean, not sterile	Provided clean, not sterile	Unchanged from K093416/K092043
<i>Anatomical Sites</i>	Total Face Mask, covering the eyes, nose and mouth	Nasal interface, covering only the nose	Unchanged from K092043

(b)(4) Product Specs



(b)(4)Product Specs



VI. Labeling

Draft labeling is provided in TAB 13 of the original submission. This section includes the instructions for use, warning and caution statements, device specifications, and reuse instructions (disinfection). The caution statement for prescription devices as required by 21 CFR 801.109: Caution: "Federal law restricts this device to sale by or on the order of a physician. Appropriate caution and warning statement related to the usage of the device are included.

VII. Sterilization/Shelf Life/Reuse

The device is not provided sterile and is it intended to be sterilized using (b) (4)

VIII. Biocompatibility

A skin contacting and gas pathway materials have been evaluated in accordance with the guidance provided in ISO-10993-1. A declaration of conformity to ISO-10993-1 is provided in Tab 9 of the original submission.

IX. Software

This device has no software, this section is not applicable.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The device has not electrical or mechanical systems, this section is not applicable.

XI. Performance Testing – Bench

The following is a summary of the bench testing that was performed on the PerforMax Pediatric EE Total Face Mask.

(b)(4)Product Specs

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

[Redacted]

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Environmental Testing

Per the guidance in the FDA Reviewer Guidance for Premarket Notification Submissions, November 1993, testing will be performed to demonstrate safety and effectiveness of the performance characteristics of the device in the intended environment of use and post-storage conditioning. The Intent to Declare Conformance is provided in Tab 9C and test matrix per Appendix A of FDA Reviewer Guidance for Premarket Notification Submissions, November 1993, is provided in Tab 18B.

Risk Assessment

An initial hazards assessment was performed for the PerforMax Pediatric EE Total Face Mask. The assessment analyzed the use situation, the sequence of events, and harm. An initial risk level of the harm was established based on the initial severity and probability classifications (as defined in the risk management plan in Tab 18C).

XII. Performance Testing – Animal

N/A Animal testing not needed to determine substantial equivalence.

XIII. Performance Testing – Clinical

N/A Clinical testing was not submitted to determine substantial equivalence. Submission only has a reference to a clinical study performed in 2000.

XIV. Substantial Equivalence Discussion

	Yes	No
1. Same Indication Statement?	<input checked="" type="checkbox"/>	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	<input type="checkbox"/>	If YES = Stop NSE
3. Same Technological Characteristics?	<input type="checkbox"/>	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	<input type="checkbox"/>	If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	<input type="checkbox"/>	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?	<input type="checkbox"/>	If YES = Stop NSE
7. Accepted Scientific Methods Exist?	<input type="checkbox"/>	If NO = Stop NSE
8. Performance Data Available?	<input type="checkbox"/>	If NO = Request Data
9. Data Demonstrate Equivalence?	<input type="checkbox"/>	Final Decision:

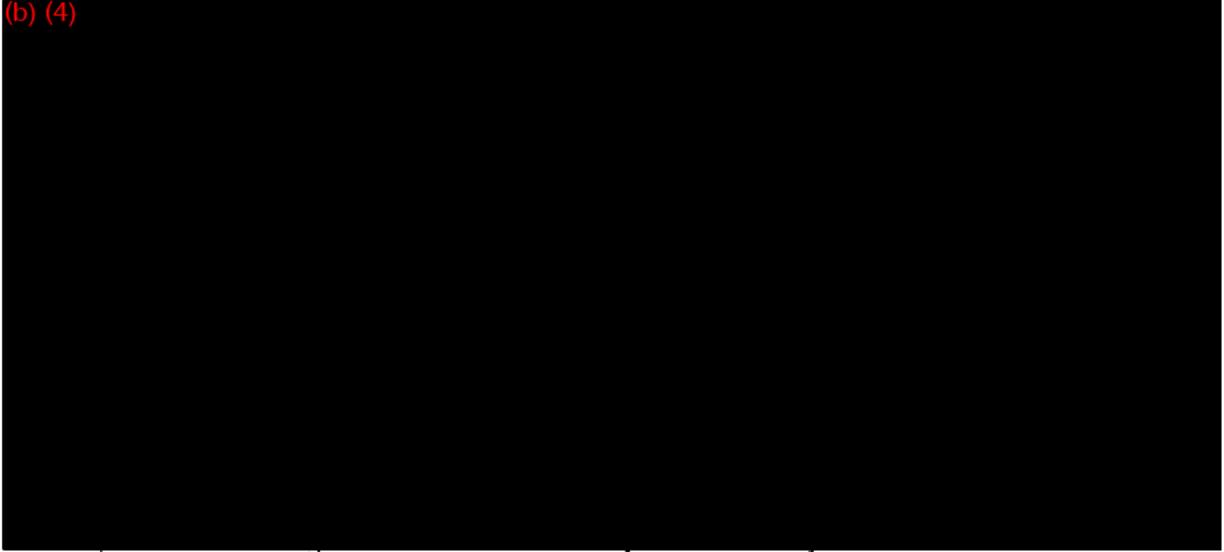
Note: See

http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. 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:
Additional information regarding the verification and validation activities is needed in order to determine substantial equivalence.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not 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:

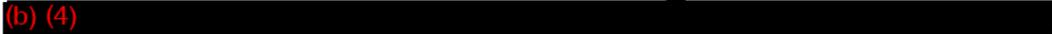
XV. Deficiencies

(b) (4)



XVI. Contact History

(b) (4)



XVII. Recommendation

I recommend that the file be placed on hold pending the receipt of additional information.

Regulation Number: 21 CFR

Regulation Name:

Regulatory Class: Class I, II, III, or Unclassified

Product Code:



James Lee PhD, Lead Reviewer



Lex Schultheis, MD, PhD, ARDB Branch Chief

3/27/12
Date

3/27/12
Date



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

February 24, 2012

RESPIRONICS, INC.
SLEEP AND HOME RESPIRATORY GROUP
365 PLUM INDUSTRIAL COURT
PITTSBURGH, PENNSYLVANIA 15239
ATTN: MICHELLE BRINKER

510k Number: K120562

Received: 2/24/2012

Product: PERFORMAX PEDIATRIC EE TOTAL F

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

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

Mcdonald, Lisa *

From: Microsoft Outlook
To: 'michelle.brinker@philips.com'
Sent: Friday, February 24, 2012 3:02 PM
Subject: Relayed: K120562 ACK Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'michelle.brinker@philips.com'

Subject: K120562 ACK Letter

Sent by Microsoft Exchange Server 2007

TABLE OF CONTENTS**PERFORMAX PEDIATRIC EE TOTAL FACE MASK – TRADITIONAL 510(K)**

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K-21



The medical device user fee cover sheet is provided following this page.

(Please turn the page.)

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover-sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) RESPIRONICS INC 1001 Murry Ridge Lane Murrysville PA 15668 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****4989		2. CONTACT NAME Zita Yurko 2.1 E-MAIL ADDRESS Zita.Yurko@Philips.com 2.2 TELEPHONE NUMBER (include Area code) 724-387-4120 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 724-387-7490	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type:			
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input checked="" type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes 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 the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION \$0.00		30-Jan-2012	

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

000003



The CDRH Premarket Review Submission cover sheet is provided following this page.

(Please turn the page.)

000004

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
 OMB No. 0910-0120
 Expiration Date: December 31, 2013
 See OMB Statement on page 5.

Date of Submission 02/21/2012	User Fee Payment ID Number (b) (4)	FDA Submission Document Number (if known)
----------------------------------	---------------------------------------	---

SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Respironics, Inc.		Establishment Registration Number (if known) 2518422	
Division Name (if applicable) Sleep and Home Respiratory Group		Phone Number (including area code) (724) 387-4146, (b) (4)	
Street Address 365 Plum Industrial Court		FAX Number (including area code) (724) 387-3999	
City Pittsburgh	State / Province PA	ZIP/Postal Code 15239	Country USA
Contact Name Michelle Brinker			
Contact Title Regulatory Affairs Manager, Patient Interface		Contact E-mail Address Michelle.Brinker@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	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (specify):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (specify):

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
--	---	---

Other Reason (specify):

000006

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	MNS	2	CBK	3		4		
5		6		7		8		

Information on devices to which substantial equivalence is claimed (if known)			
	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K092043	BiPAP Synchrony 2 (PerforMax Youth EE Total Face Mask)	Respironics, Inc.
2	K093416	Trilogy 200 Ventilator (Small Child Profile Lite Nasal Mask)	Respironics, Inc.
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Ventilator, Non-Continuous (Respirator)

	Trade or Proprietary or Model Name for This Device	Model Number
1	PerforMax Pediatric EE Total Face Mask	1
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 BZD	C.F.R. Section (if applicable) 21 CFR 868.5905	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Anesthesiology		

Indications (from labeling)
 PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number (if known)

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Respironics, Inc.		Establishment Registration Number 2518422		
Division Name (if applicable) Sleep and Home Respiratory Group		Phone Number (including area code) (724) 387-4146, (b) (6)		
Street Address 1001 Murry Ridge Lane		FAX Number (including area code) (724) 387-3999		
City Murrysville		State / Province PA	ZIP Code 15668	Country USA
Contact Name Michelle Brinker		Contact Title Regulatory Affairs Manager, Patient Interface		Contact E-mail Address Michelle.Brinker@philips.com

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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

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	AAMI ANSI ISO	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process	2009	
2	14971	AAMI ANSI ISO	Medical devices – Application of risk management to medical devices	2007	
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 1350 Piccard Drive, Room 400
 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.



The 510(k) Cover Letter is provided following this page.

(Please turn the page.)



21 February, 2012

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

K. Kosler
FDA CDRH DMC
FEB 24 2012
Received

RE: **Traditional 510(k) submission for the PerforMax Pediatric EE Total Face Mask**

Dear Document Control Clerk:

Respironics Inc. hereby submits this **Traditional 510(k)** for the Respironics PerforMax Pediatric EE Total Face Mask. The PerforMax Pediatric EE Total Face Mask is a modification in design to the Respironics PerforMax Youth EE Total Face Mask (previously cleared under K092043) and Respironics Small Child Profile Lite Nasal Mask (previously cleared under K093416). The modifications consist of the following:

1. Updated environment to restrict to hospital/institutional use only
2. Reduced size of the faceplate and cushion
3. Modified elbow
4. Modified the mask operating pressure range, replaced unintentional leak specification with total mask leak specification, and added inspiratory and expiratory resistance specification
5. Material changes for the elbow hub, elbow body, and headgear

Like the existing products, the modified device is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The PerforMax Pediatric EE Total Face Mask is for patients 1 year or older (> 7 kg). The mask is for multi-patient use in the hospital / institutional environment only.

It is our conclusion, based on the information contained within this submittal, that the device modifications discussed herein, has no affect on the fundamental scientific technology and safety or effectiveness of the device. In accordance with the FDA Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)'s, the following information is provided to address the principal factors of the design and use of the PerforMax Pediatric EE Total Face Mask. 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*
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

*The mask, excluding the elbow, is intended for multi-patient use. The elbow is a single use disposable component.

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 contact me by phone at (724) 387-4146 (w), (b) (4), (724) 387-3999 (fax) or by email at michelle.brinker@philips.com.

Sincerely,

(b) (6)

Michelle Brinker
 Manager, Regulatory Affairs
 Patient Interface

000012

TAB 4

INDICATIONS FOR USE STATEMENT

The indications for use statement is provided following this page.

(Please turn the page.)

Indications for Use

510(k) Number (if known): _____

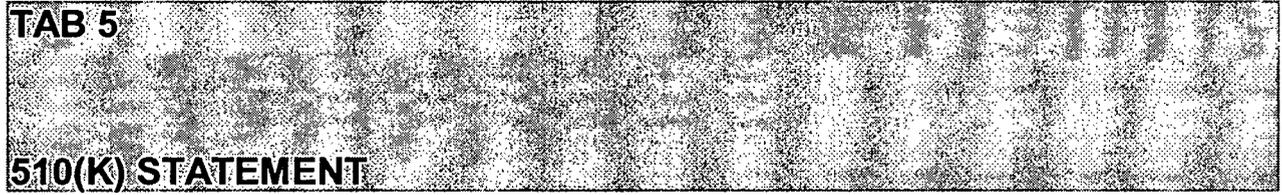
Device Name: PerforMax Pediatric EE Total Face Mask

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



The 510(k) Statement is provided following this page.

(Please turn the page.)



PREMARKET NOTIFICATION 510(k) STATEMENT

Pursuant to 21 CFR 807.93, I certify that, in my capacity as Manager of Regulatory Affairs of Respironics, Inc. I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(b) (6)

(Signature)

Michelle Brinker
(Typed Name)

2-17-2012
(Date)

(Premarket Notification 510(k) Number)

TAB 6

TRUTHFUL AND ACCURATE STATEMENT

The Truthful and Accurate Statement as required by 21CFR 807.87(k) is provided following this page.

(Please turn the page.)



**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**

Pursuant to 21 CFR 807.87 (k), I, Michelle Brinker, certify that, in my capacity as Manager of Regulatory Affairs of Respironics, Inc., 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.

(b) (6)

(Signature)

Michelle Brinker

(Typed Name)

2-21-2012

(Date)

(Premarket Notification 510(k) Number)



This section does not apply. The Respironics Performax Pediatric EE Total Face Mask is a Class II device.

(End of Tab.)

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.)

TAB 9
DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

This section contains the Declaration of Conformity, forms, and summary reports to demonstrate conformity to the following standards:

Tab 9A	ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
	<ul style="list-style-type: none"> • Declaration of Conformity
	<ul style="list-style-type: none"> • FORM FDA 3654 Standards Data Report for 510(k)s
	<ul style="list-style-type: none"> • Summary Report
Tab 9B	ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices
	<ul style="list-style-type: none"> • Declaration of Conformity
	<ul style="list-style-type: none"> • FORM FDA 3654 Standards Data Report for 510(k)s
	<ul style="list-style-type: none"> • Summary Report
Tab 9C	FDA Reviewers Guidance for Pre-market notification submissions – November 1993 (clause (i) Performance Requirements – Mechanical and Environmental (6) High and Low Temperature and Humidity)
	<ul style="list-style-type: none"> • Intent to Declare Conformity

(Please turn the page.)

Tab 9A

Declaration of Conformity to

ISO 10993-1: 2009 Biological Evaluation

of Medical Devices – Part 1: Evaluation and testing

within a risk management process



**Declaration of Conformity to
ISO 10993-1: 2003 Biological evaluation of medical devices
Part 1: Evaluation and testing
PerforMax Pediatric EE Total Face Mask**

We,

Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550 USA,

Declare that,

The Respironics PerforMax Pediatric EE Total Face Mask components are categorized, per the standard, as "surface devices" that have contact duration of C (> 30 days cumulative use).

Component Certification:

Mask Component (See Figure below)	Material Grade	Patient Contact	Tests Performed
Faceplate	(b) (4)		
Cushion			
Elbow Hub			
Split Washer			

Entrainment Elbow Body (EE Leak 1)	(b) (4)
Entrainment Elbow Body (EE Leak 2)	
Entrainment valve flapper	
Port Cap	
Headgear Clip	
Headgear Material (headgear not pictured below)	
Flexible Tubing	
Hose Swivel	

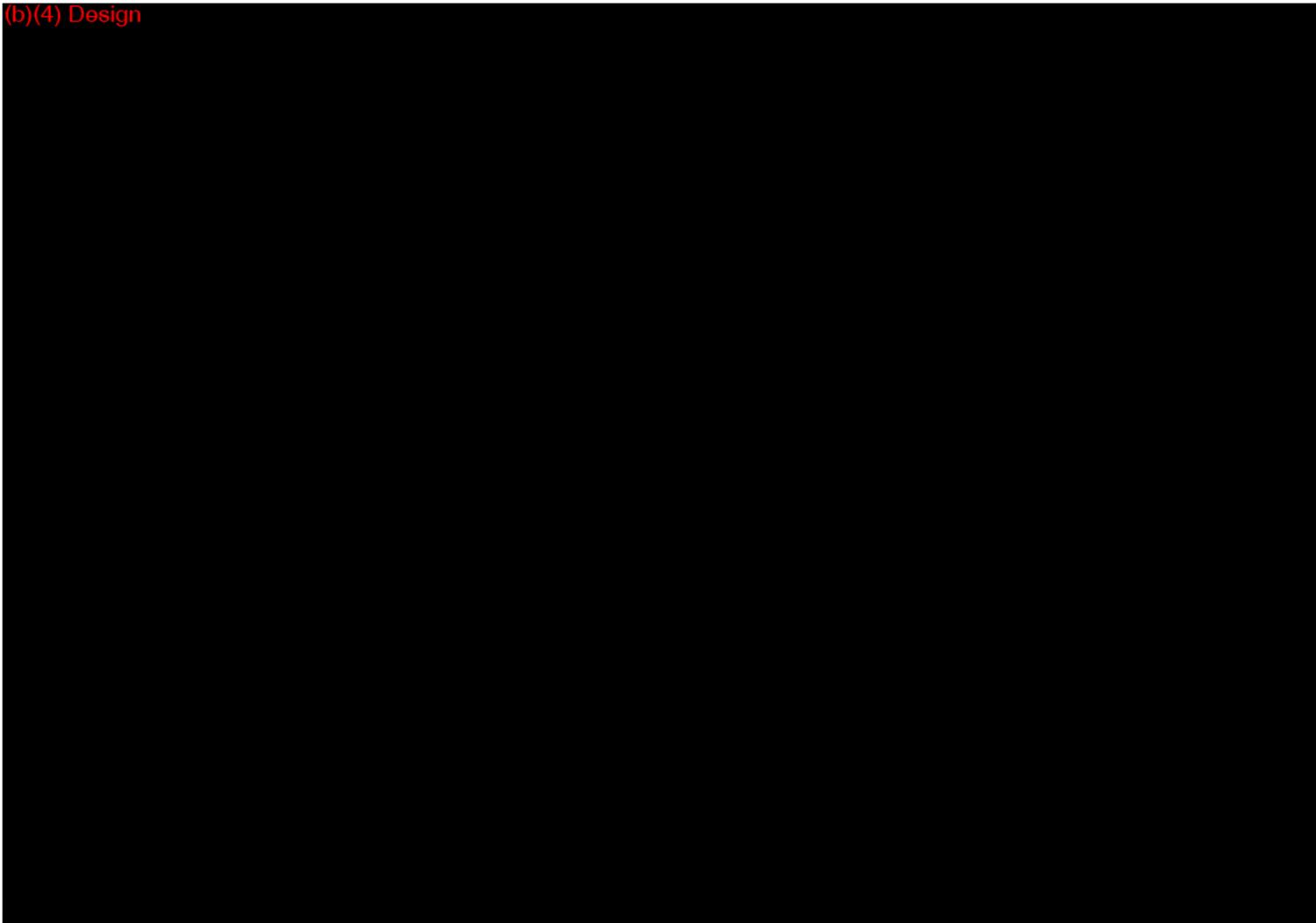
(b) (6)

Michelle Brinker
Regulatory Affairs Manager
Patient Interface

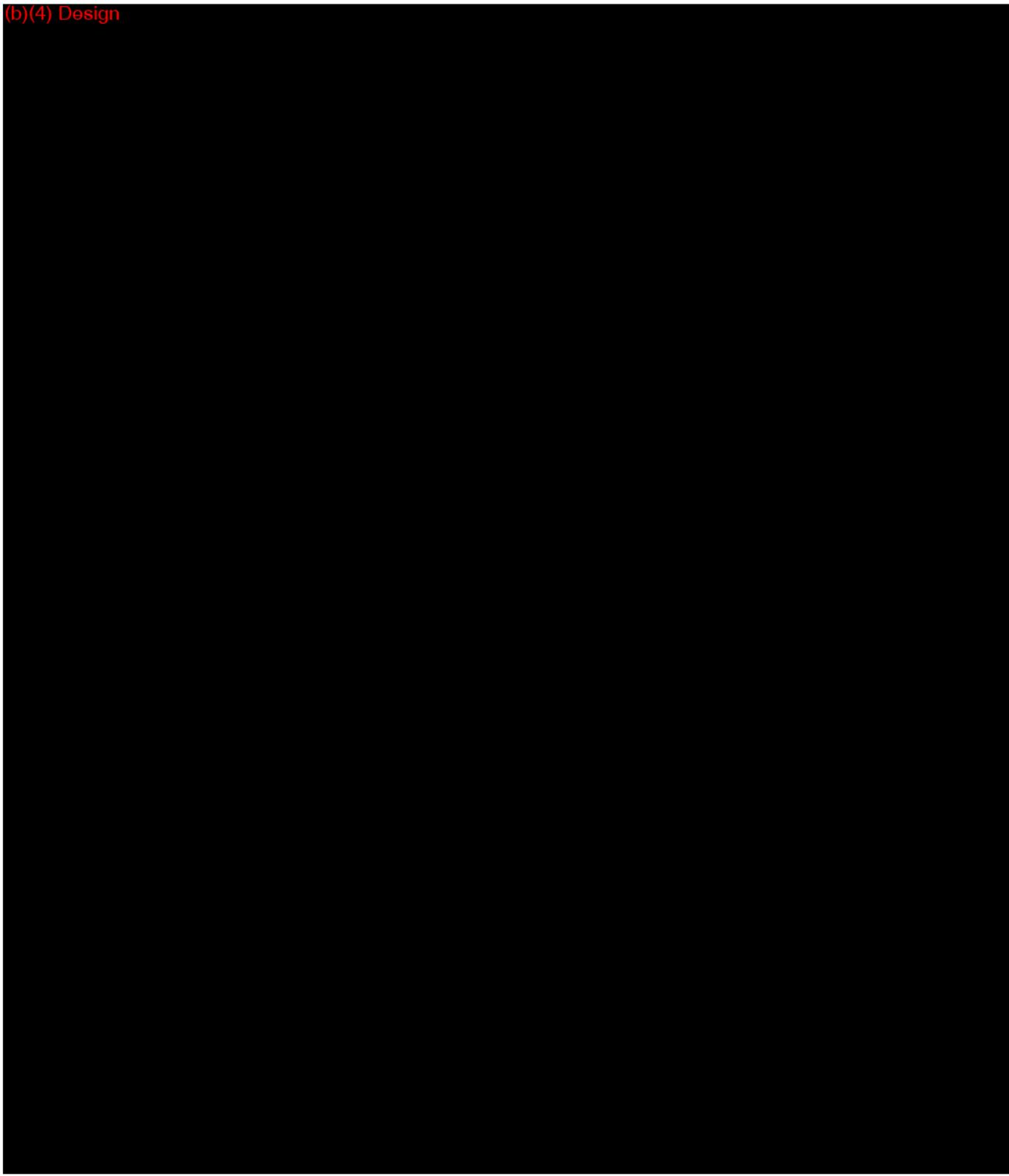
2-21-2012

Dated: February 21, 2012

(b)(4) Design



(b)(4) Design



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 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-156

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: Use of International Standard ISO-10993 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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
See Summary Report on next page

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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.

PerforMax Pediatric EE Total Face Mask Summary Report

Conformance to ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

Section 1: Scope
No Requirements

■ Section 2: Normative References
No Requirements

■ Section 3: Terms and Definitions
No Requirements

Section 3.1: Medical Device
No Requirements

Section 3.2: Material
No Requirements

Section 3.3: Final Product
No Requirements

Section 3.4: Chemical Constituent
No Requirements

Section 3.5: Data Set
No Requirements

■ Section 4: General Principles Applying to Biological Evaluation of Medical Devices

Section 4.1:
No Deviations.

All patient gas path materials and skin contact only materials used in the mask were evaluated in accordance with the guidance provided by this standard.

(b)(4) Testing

A large black rectangular redaction box covers the majority of the page content below the text "(b)(4) Testing".

(b)(4) Testing



(b)(4) Testing



Section 4.2:

No Deviations. See explanation included in Section 4.1.

Section 4.3:

No Deviations. See explanation included in Section 4.1.

Section 4.4:

No Deviations. See explanation included in Section 4.1.

Section 4.5:

No Deviations. See explanation included in Section 4.1.

Section 4.6:

No Deviations. See explanation included in Section 4.1.

Section 4.7:

No Deviations. See explanation included in Section 4.1.

Section 4.8:

No Deviations. See explanation included in Section 4.1.

■ Section 5: Categorization of Medical Devices

Section 5.1: General

No Deviations

Section 5.2: Categorization by Nature of Body Contact

Section 5.2.1: Surface-contacting Devices

The materials used in the mask are classified as skin contacting. These materials do not contact intact mucosal membranes or breached or compromised surfaces.

Section 5.2.2: External Communicating Devices
Not Applicable.

Section 5.2.3: Implant Devices
Not Applicable.

Section 5.3: Categorization by Duration of Contact
The materials have the potential to be used for cumulative long-term use and as such are classified as contact duration C.

■ Section 6: Biological Evaluation Process

Section 6.1: Material Characterization
No Deviations.

Section 6.2: Biological Evaluation Tests

Section 6.2.1: General
No Deviations.

Section 6.2.2: Test Descriptions

Section 6.2.2.1: General
No Deviations

Section 6.2.2.2: Cytotoxicity
No Deviations.

Section 6.2.2.3: Delayed-type hypersensitivity (Sensitization)
No Deviations.

Section 6.2.2.4: Irritation (including intracutaneous reactivity)
No Deviations.

Section 6.2.2.5: Systemic Toxicity (Acute Toxicity)
Not Applicable.

Section 6.2.2.6: Subacute and Subchronic Toxicity
Not Applicable.

Section 6.2.2.7: Genotoxicity

Not Applicable.

Section 6.2.2.8: Implantation

Not Applicable.

Section 6.2.2.9: Haemocompatibility

Not Applicable.

Section 6.2.2.10: Chronic Toxicity

Not Applicable.

Section 6.2.2.11: Carcinogenicity

Not Applicable.

Section 6.2.2.12: Reproductive and Developmental Toxicity

Not Applicable.

Section 6.2.2.13: Biodegradation

Not Applicable.

Section 6.2.2.14: Toxicokinetic studies

Not Applicable.

Section 6.2.2.15: Immunotoxicology

Not Applicable.

■ Section 7: Interpretation of biological evaluation data and overall biological safety assessment

No Deviations

■ Annex A: Biological evaluation tests

Referenced as an informative guidance.

■ Annex B: Guidance on the risk management process

Referenced as an informative guidance.

■ Annex C: Suggested procedure for literature review

Referenced as an informative guidance.

Tab 9B

Declaration of Conformity to

ISO 14971:2007 Medical Devices –

Application of Risk Management to Medical Devices

**Declaration of Conformity to
ISO 14971:2007, Medical devices - Application of risk
management to medical devices
PerforMax Pediatric EE Total Face Mask**

We,

Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550 USA,

Declare that,

The Respironics PerforMax Pediatric EE Total Face Mask complies with ISO 14971:2007,
Medical devices - Application of risk management to medical devices.

(b) (6)


Les Edsall
Sr. Manager, Quality Assurance
and Regulatory Affairs

02-22-2012
Dated: February 21, 2012

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 14971:2007 Medical devices - Application of risk management to medical devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-40

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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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.

PerforMax Pediatric EE Total Face Mask Summary Report

ISO 14971:2007 Medical devices – Application of risk management to medical devices

- Section 1: Scope
No Requirements.
- Section 2: Terms and definitions (provided in Clause 2.1 – 2.28)
No Requirements
- Section 3: General requirements for risk management
 - Clause 3.1 – Risk management process
No Deviations
 - Clause 3.2 – Management responsibilities
No Deviations
 - Clause 3.3 – Qualification of personnel
No Deviations
 - Clause 3.4 – Risk management plan
No Deviations
 - Clause 3.5 – Risk management file
No Deviations
- Section 4: Risk analysis
 - Clause 4.1 – Risk analysis process
No Deviations
 - Clause 4.2 – Intended use and identification of characteristics related to the safety of the medical device
No Deviations
 - Clause 4.3 – Identification of hazards
No Deviations
 - Clause 4.4 – Estimation of the risk(s) for each hazardous situation
No Deviations
- Section 5: Risk evaluation

No Deviations

■ Section 6: Risk control

Clause 6.1 – Risk reduction

No Deviations

Clause 6.2 – Risk control option analysis

No Deviations

Clause 6.3 – Implementation of risk control measure(s)

No Deviations

Clause 6.4 – Residual risk evaluation

No Deviations

Clause 6.5 – Risk/benefit analysis

No Deviations

Clause 6.6 – Risks arises from risk control measures

No Deviations

Clause 6.7 – Completeness of risk control

No Deviations

■ Section 7: Evaluation of overall residual risk acceptability

No Deviations

■ Section 8: Risk management report

No Deviations

■ Section 9: Production and post-production information

No Deviations

■ Annex A: Rationale for requirements

Referenced as an informative guidance.

■ Annex B: Overview of the risk management process for medical devices

Referenced as an informative guidance.

■ Annex C: Questions that can be used to identify medical device characteristics that could impact on safety

Referenced as an informative guidance.

■ Annex D: Risk concepts applied to medical devices

Referenced as an informative guidance.

- Annex E: Examples of hazards, foreseeable sequences of events and hazardous situations

Referenced as an informative guidance.

- Annex F: Risk management plan

Referenced as an informative guidance.

- Annex G: Information on risk management techniques

Referenced as an informative guidance.

- Annex H: Guidance on risk management for *in vitro* diagnostic medical devices

Referenced as an informative guidance.

- Annex I: Guidance on risk analysis process for biological hazards

Referenced as an informative guidance.

- Annex J: Information for safety and information about residual risk

Referenced as an informative guidance.

Tab 9C

Intent to Declare Conformity to FDA Reviewers Guidance for Pre-market notification submissions – November 1993 (clause (i) Performance Requirements – Mechanical and Environmental (6) High and Low Temperature and Humidity)

**FDA Reviewers Guidance for Pre-market Submissions,
November 1993**

**Intent to Declare Conformity to Section (i) Performance
requirements – Mechanical and Environment, sub-clause (6)
High and Low Temperature and Humidity**

We,

Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550 USA,

Declare that the PerforMax Pediatric EE Total Face Mask will meet the requirements provided in section (i), sub-clause (6) (i) and (ii) such that the mask is able to operate within its specification when operating in the environmental temperature range of 5 to 40° C and in the environmental humidity range of 15 to 95% RH, non-condensing. Additionally, the device will not be damaged and will remain operational within its specification after storage in the environmental temperature range of -20 to +60C and at a relative humidity up to 95% RH, non-condensing.

Supporting data will be available before marketing the device.

(b) (6)

2/17/12

Mark Cortese
Manager, Design V&V

Date

TAB 10
EXECUTIVE SUMMARY



Original Date of Submission	21 February 2012
Device Trade Name	Respironics PerformMax Pediatric EE Total Face Mask
Common/Usual Name	Face Mask
Establishment Registration #	2518422
Address of Mfr. Facility	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-4146 FAX (724)-387-3999 Cell (412) 209-8665
Classification	Class II device
Classification Panel	Anesthesiology Devices
Classification Reference	21 CFR 868.5905
Product Code	BZD – Ventilator, Non-Continuous (Respirator)
Predicate Device(s)	Respironics PerformMax Youth EE Total Face Mask (K092043) Respironics Small Child Profile Lite Nasal Mask (K093416)

Intended Use

Performax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Device Description

The Performax Pediatric EE Total Face Mask expands upon the existing Respironics Performax product line, which currently includes a size cleared for patients 7 years and older (> 18.2 kg).

The Performax Pediatric EE Total Face Mask consists of a (b) (4) faceplate, a silicone cushion that seals along the perimeter of the face, an elbow with an integral entrainment valve, and an elbow hub that retains the elbow. A pressure-pick off port is located on the elbow body. The mask is secured to the head with a bonnet style headgear.

The Performax elbow hub allows the medical professional to use the mask with either an Entrainment Elbow (EE) Leak 2 or an Entrainment Elbow (EE) Leak 1. The EE Elbow is a simple press fit assembly into the hub of the mask.

(b) (4)

(b) (4)

The EE Leak 2 elbow has a 6" fixed 15 mm to 22 mm flexible extension tube attached (see Figure 1 and 2). There is a 22 mm swivel connector at the end of the tubing to attach to standard 22 mm tubing used with CPAP and bi-level systems. The EE Leak 1 elbow connects directly to standard 22 mm tubing used with CPAP and bi-level systems (see Figure 3). The EE Leak 1 elbow does not include an extension tube or swivel.

The Performax Pediatric EE Total Face Mask is available in two sizes, XS and XXS.

Performance Data

Design verification activities were performed on the Respironics Performax Pediatric EE Total Face Mask as required by the risk analysis and product requirements. All tests confirmed that the Respironics Performax Pediatric EE Total Face Mask met the acceptance criteria.

The Respironics PerforMax Pediatric EE Total Face Mask:

- Complies with the applicable standards and requirements referenced in Tab 9
- Verification testing was performed to assure functionality of the device design and intended use. Test reports are provided in Tab 14 and 18.
- Risk Based testing was performed to assure that all hazards identified by the risk analysis are successfully mitigated. The Risk Analysis is provided in Tab 18.

Substantial Equivalence

This premarket notification submission demonstrates that the PerforMax Pediatric EE Total Face Mask is substantially equivalent to the combination of the design of the Respironics PerforMax Youth EE Total Face Mask (K092043) and Respironics Small Child Profile Lite Nasal Mask (K093416). Based on the results of the risk analysis and verification testing performed, none of the design modifications affect the safety or effectiveness of the device.

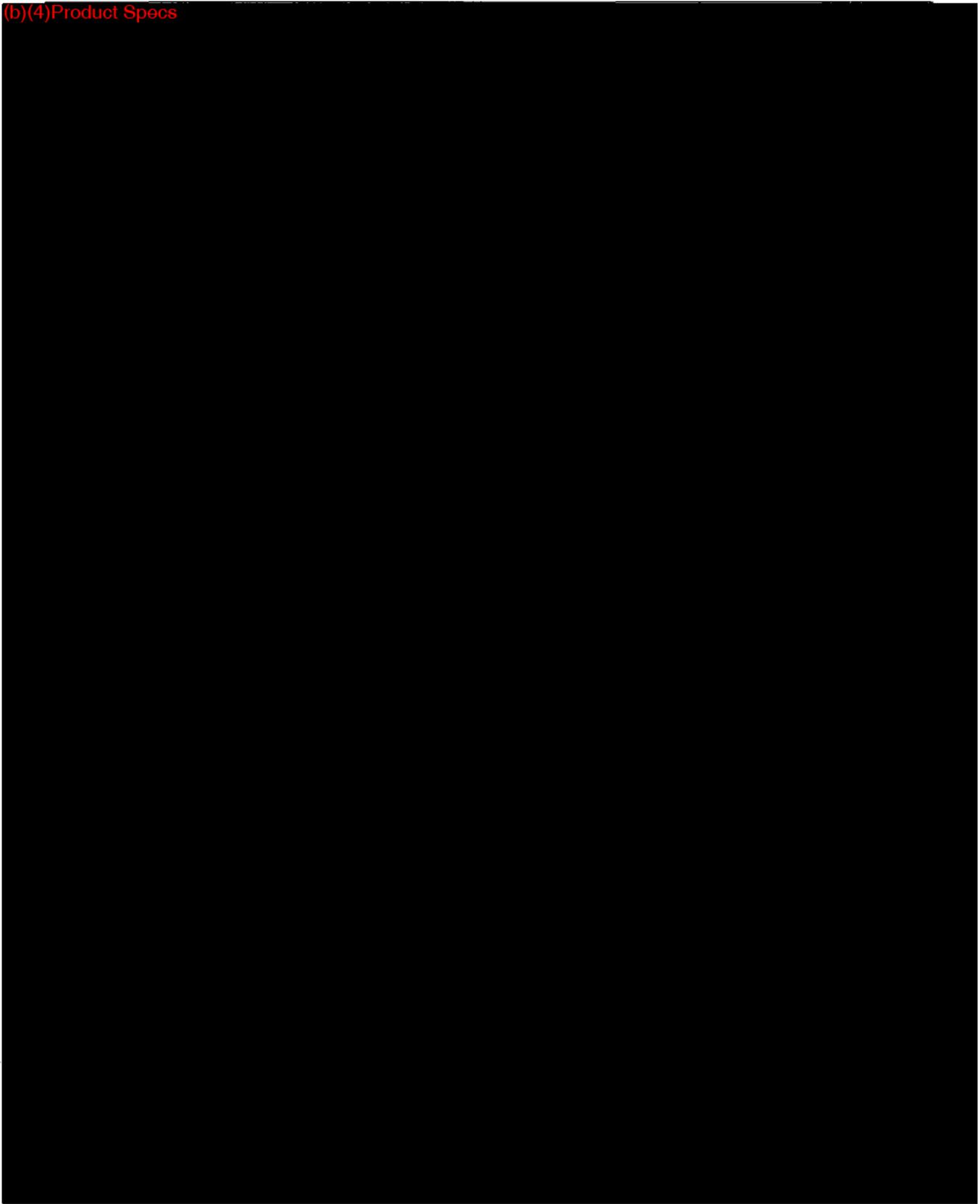
Table 10-1 below compares the PerforMax Pediatric EE Total Face Mask with the legally marketed predicate devices.

Table 10-1 Device Comparison

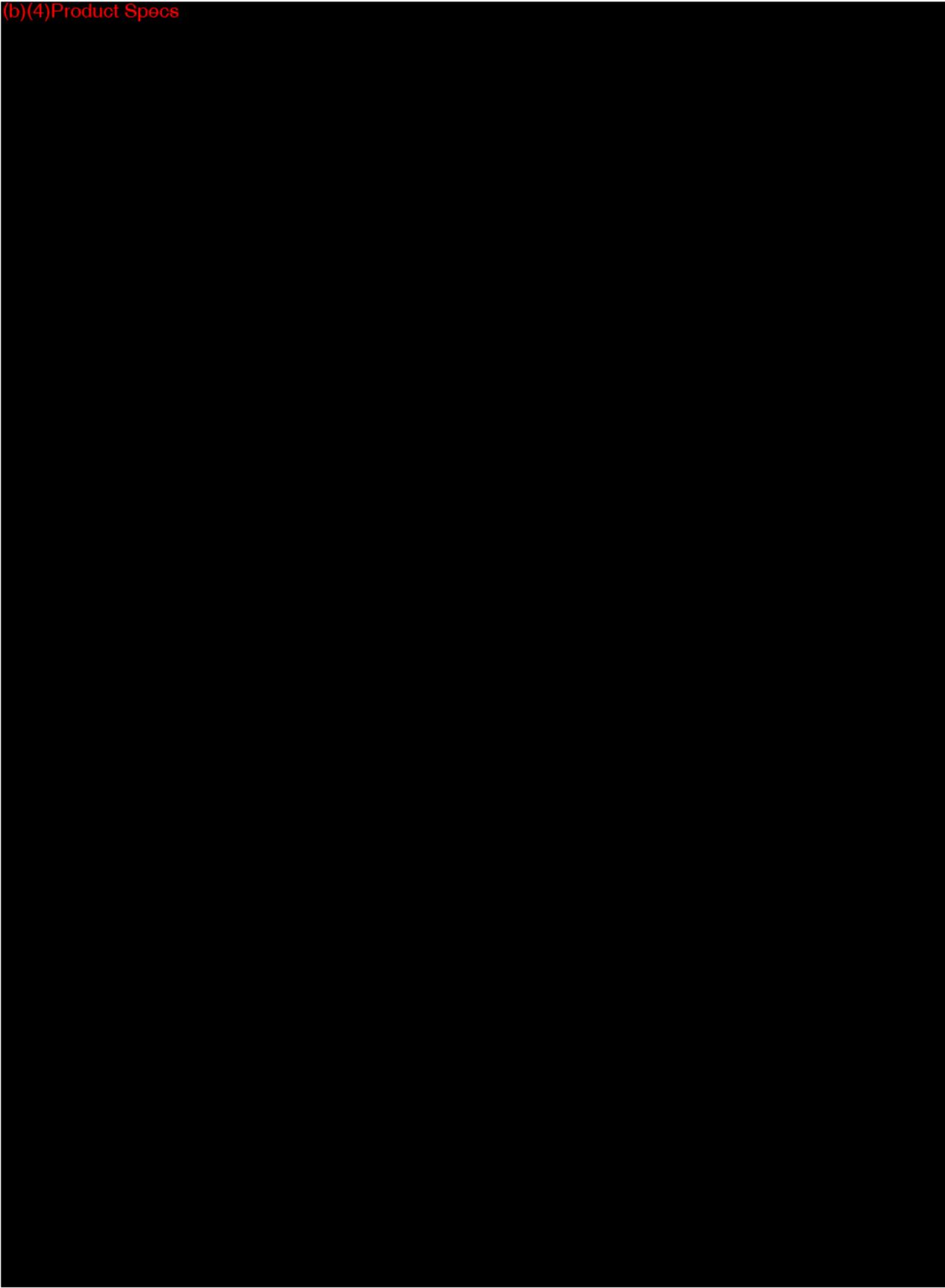
	Primary Predicate Device:	Secondary Predicate Device:	Subject Device:
	Device: Performax Youth EE Total Face Mask Manufacturer: Respironics, Inc. 510(k) Number: K092043	Device: Small Child Profile Lite Nasal Mask Manufacturer: Respironics, Inc. 510(k) Number: K093416	Device: Performax Pediatric EE Total Face Mask Manufacturer: Respironics, Inc. 510(k) Number: To be determined
<i>Intended Use submitted in labeling</i>	The Performax Youth EE Total Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients.	The Small Child Profile Lite Nasal Mask and Softcap are intended to provide an interface when used with CPAP or bi-level therapy.	Similar to K092043 and K093416 Performax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system.
<i>Patient Population</i>	7 years or older (> 18.2 kg)	1 year or older (> 7 kg)	Unchanged from K093416
<i>Environment of Use of the System</i>	Home or Hospital/institutional	Home or hospital/institutional	Hospital/institutional only
<i>Patient Usage Type</i>	Single Patient use in the home and Multi-patient use in the hospital/institutional environment	Single Patient Use	Unchanged from K092043 in the Hospital/institutional environment
<i>Product Code</i>	MNS	CBK	BZD
<i>Provided Sterile or Non-Sterile</i>	Provided clean, not sterile	Provided clean, not sterile	Unchanged from K093416/K092043
<i>Anatomical Sites</i>	Total Face Mask, covering the eyes, nose and mouth	Nasal interface, covering only the nose	Unchanged from K092043

(b) (4)

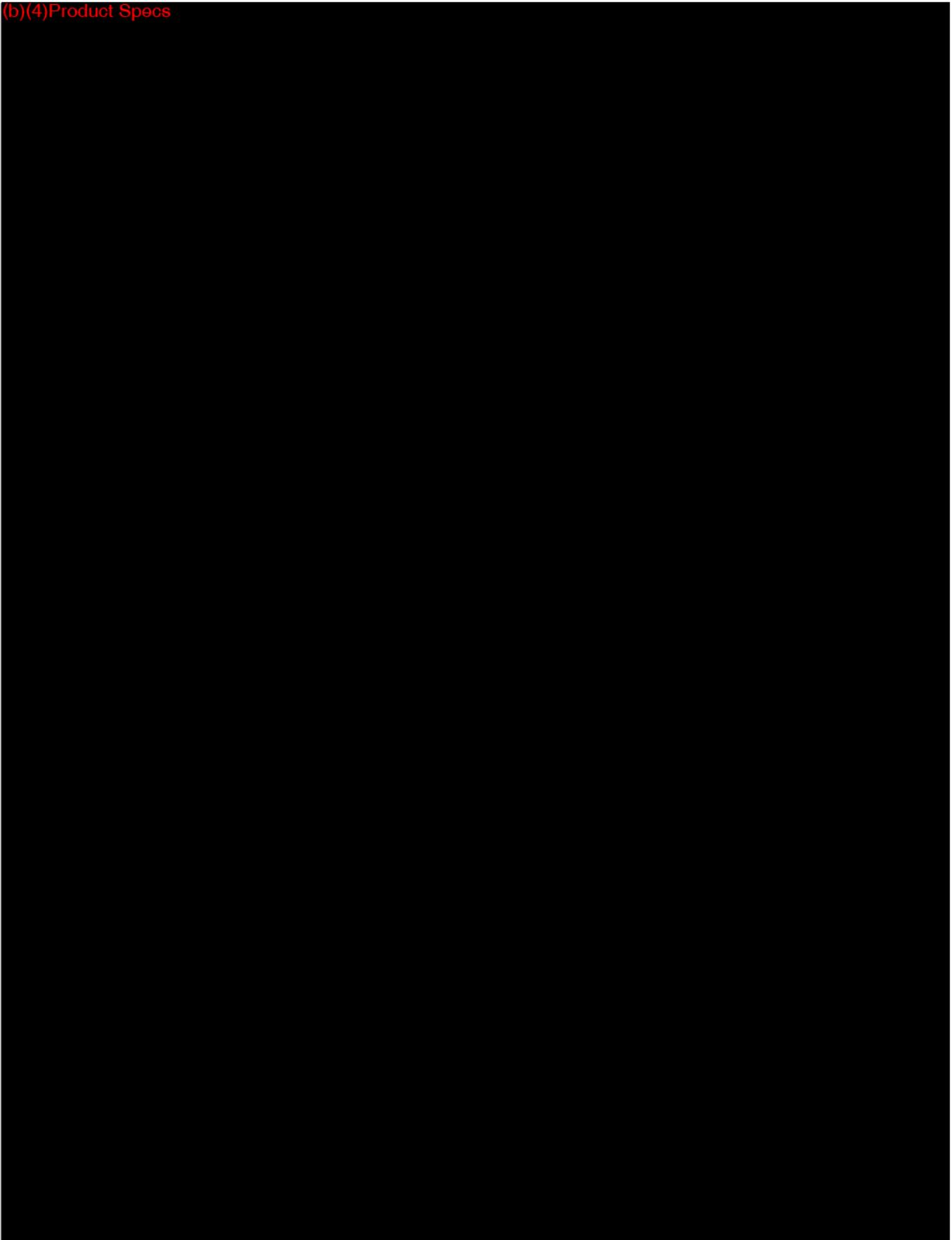
(b)(4)Product Specs



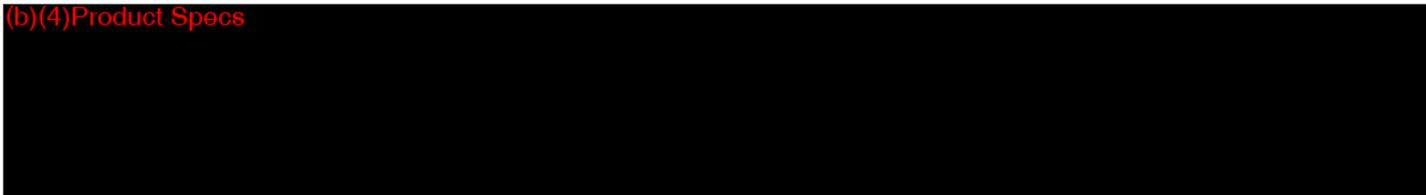
(b)(4)Product Specs



(b)(4)Product Specs



(b)(4)Product Specs



TAB 11

DEVICE DESCRIPTION

Intended Use

PerformMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Mask Description

The PerformMax Pediatric EE Total Face Mask expands upon the existing Respironics PerformMax product line, which currently includes a size cleared for patients 7 years and older (> 18.2 kg).

The PerformMax Pediatric EE Total Face Mask consists of a (b)(4)Product faceplate, a silicone cushion that seals along the perimeter of the face, an elbow with an integral entrainment valve, and an elbow hub that retains the elbow (see Figures 1 – 3) A pressure-pick off port is located on the elbow body (see Figures 4 and 5). The mask is secured to the head with a bonnet style headgear (see Figure 6).

The PerformMax elbow hub allows the medical professional to use the mask with either an Entrainment Elbow (EE) Leak 2 or an Entrainment Elbow (EE) Leak 1. The EE Elbow is a simple press fit assembly into the hub of the mask.

(b)(4)Product Specs

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

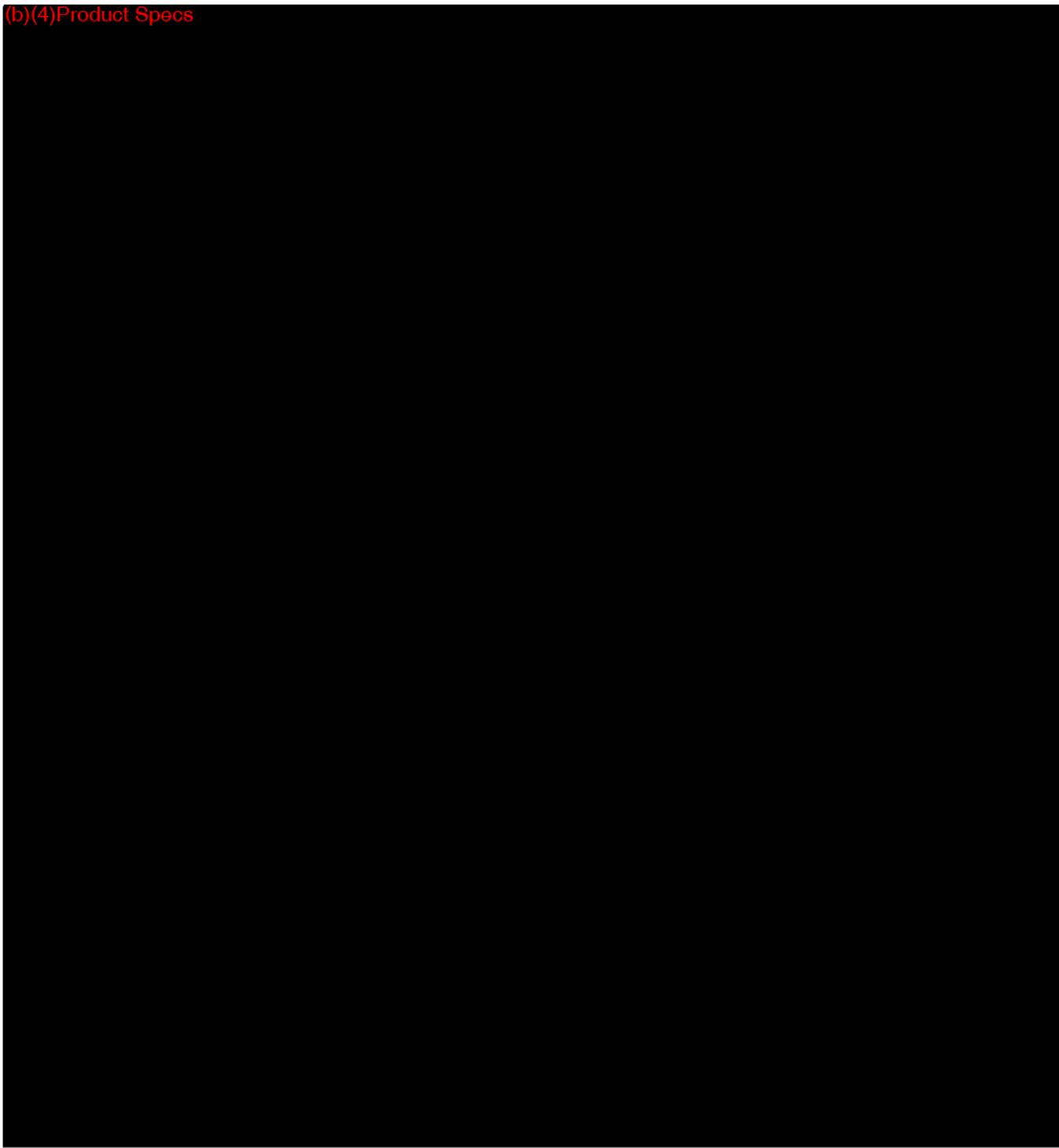
[REDACTED]

The EE Leak 2 elbow has a 6" fixed 15 mm to 22 mm flexible extension tube attached (see Figure 1 and 2). There is a 22 mm swivel connector at the end of the tubing to attach to standard 22 mm tubing used with CPAP and bi-level systems. The EE Leak 1 elbow connects directly to standard 22 mm tubing used with CPAP and bi-level systems (see Figure 3). The EE Leak 1 elbow does not include an extension tube or swivel.

The PerformMax Pediatric EE Total Face Mask is available in two sizes, XS and XXS.

Physical Characteristics

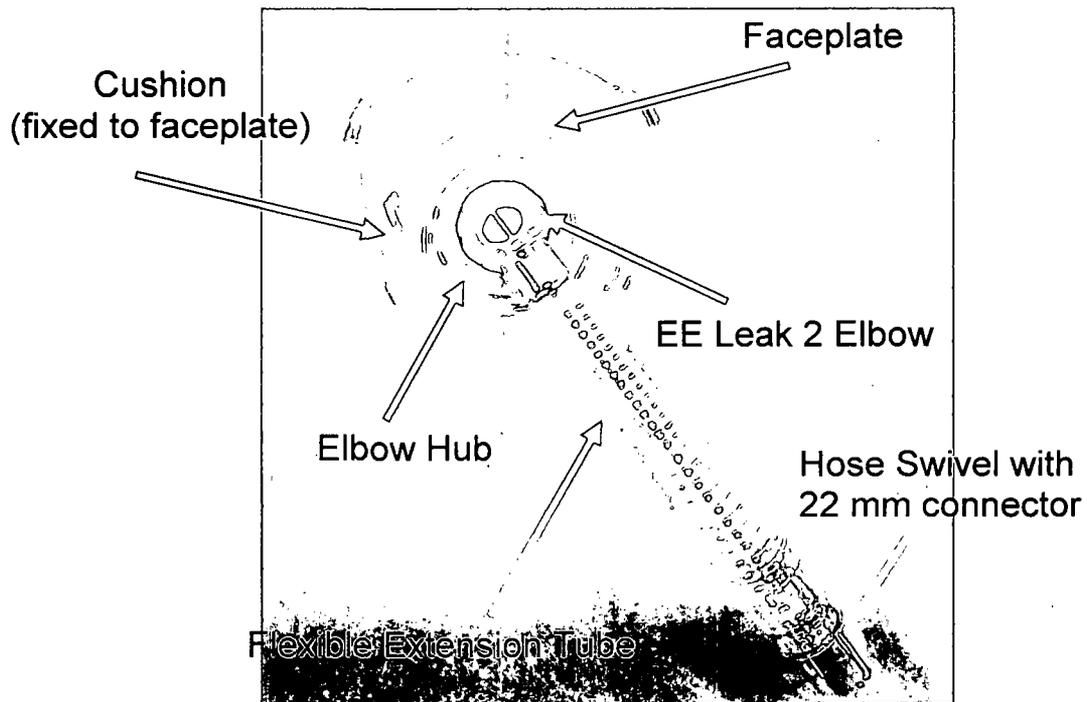
(b)(4)Product Specs



Figures

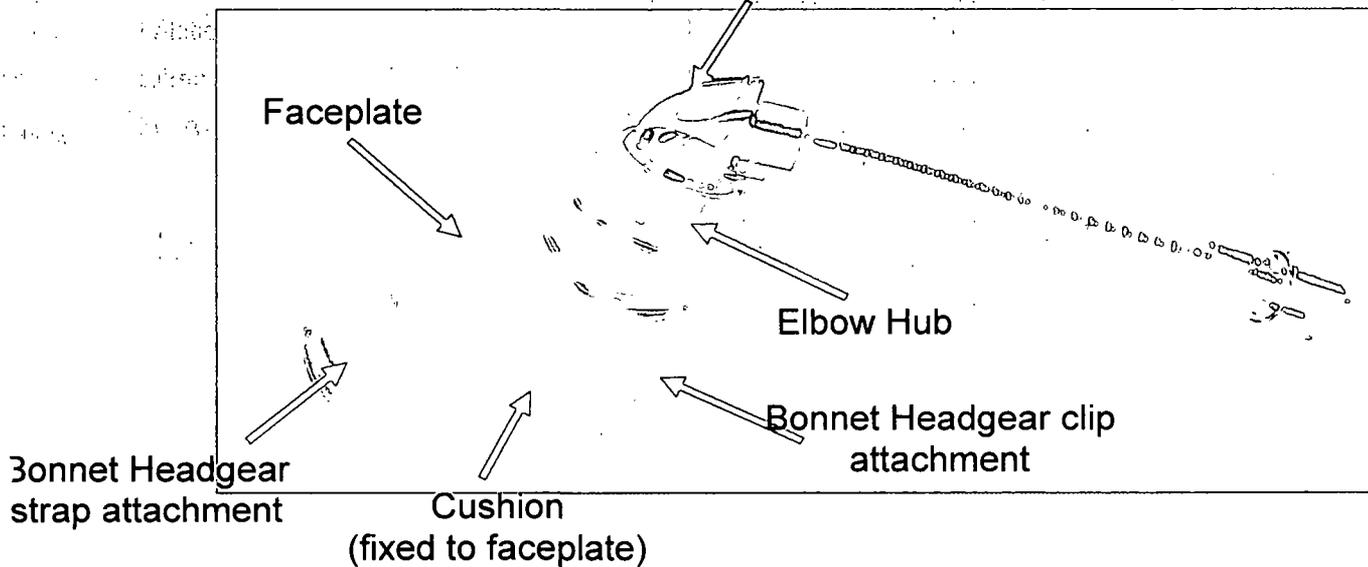
Figure 1: Performax Pediatric EE Total Face Mask
(XS size shown with EE Leak 2 Elbow)

1A Front View



1B Side View

EE Leak 2 Elbow



1C Rear View

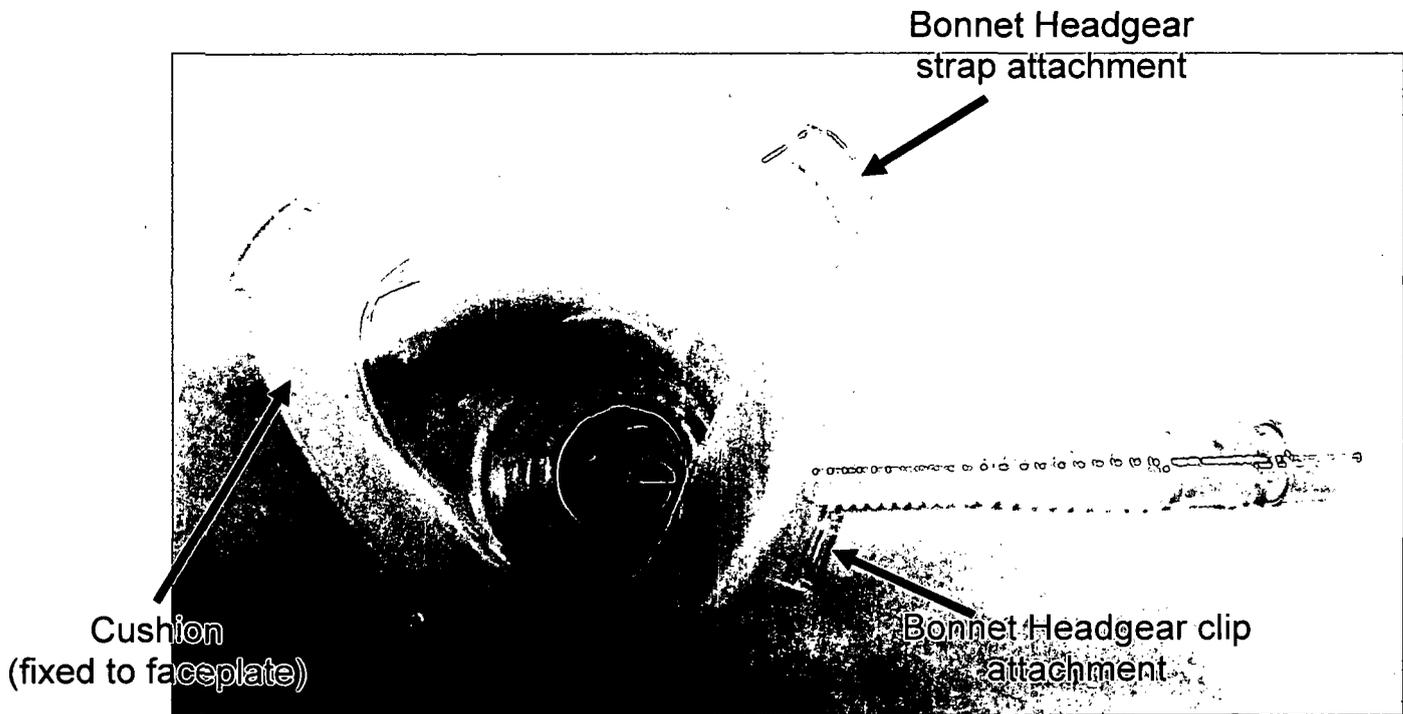
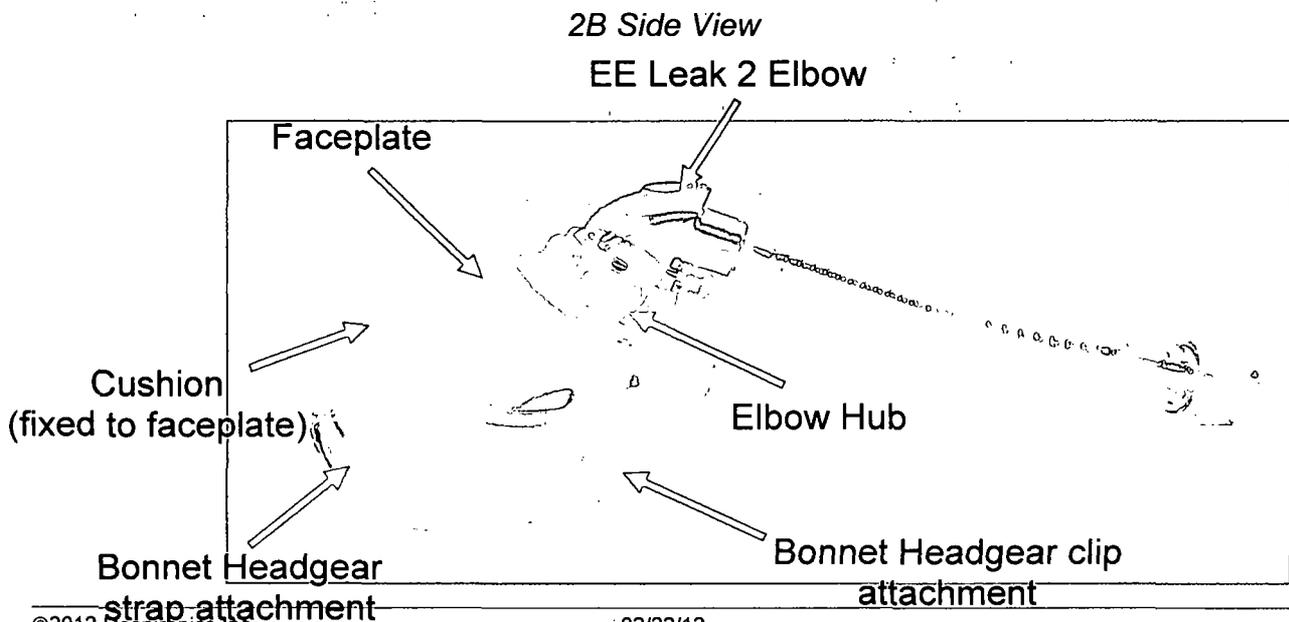
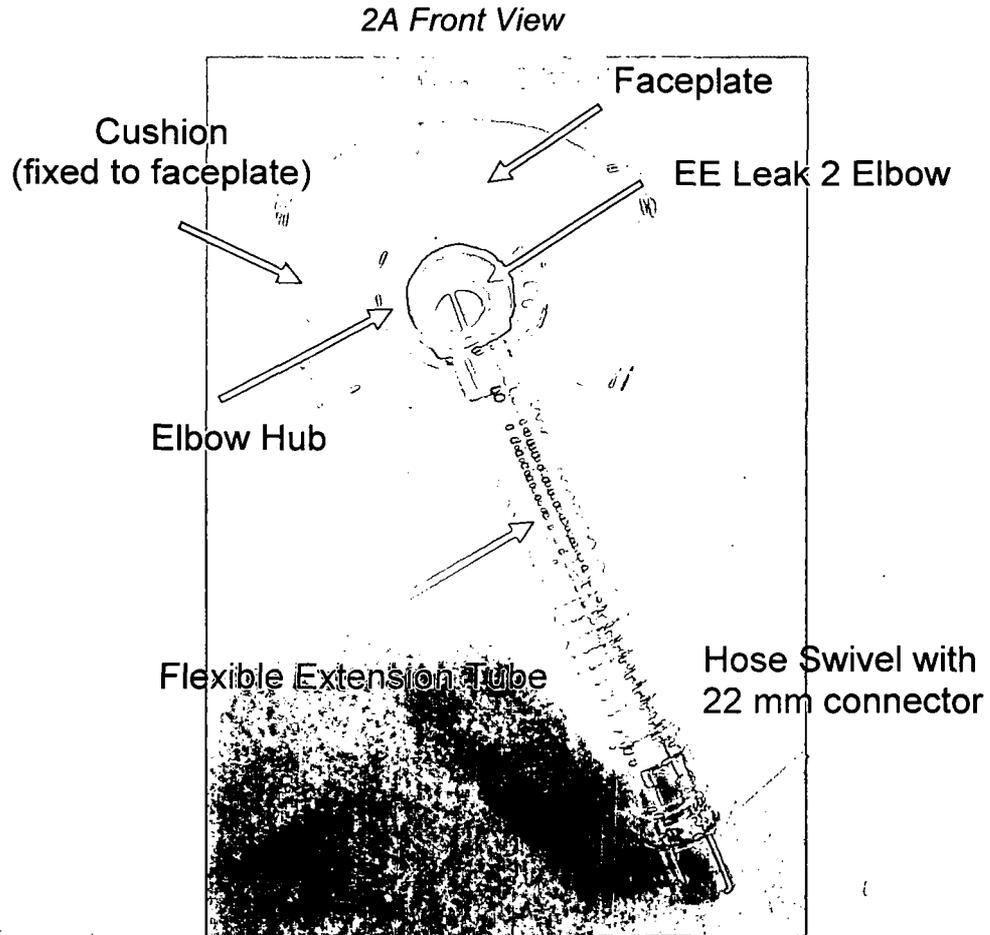
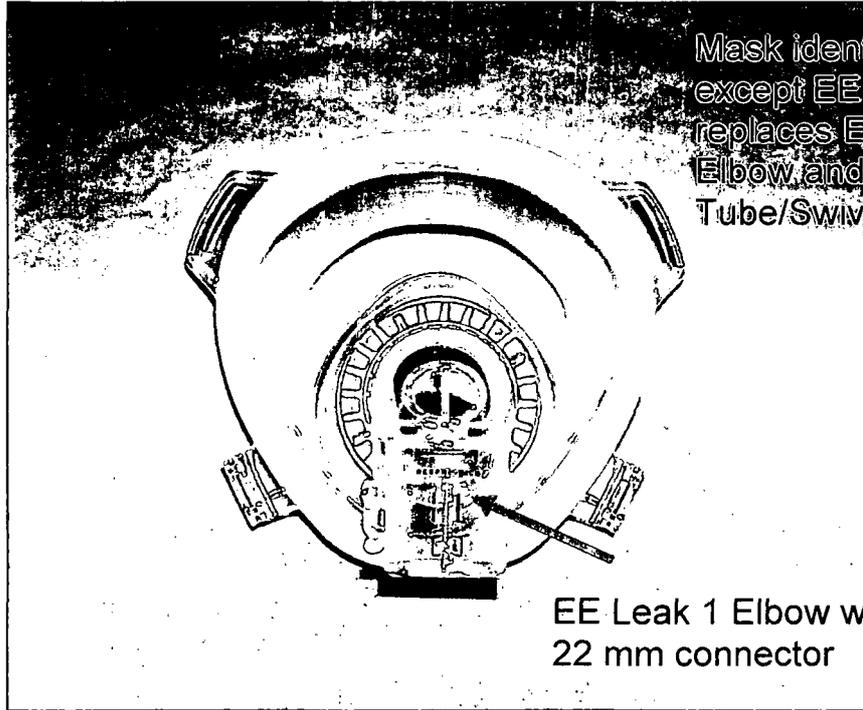


Figure 2: Performax Pediatric EE Total Face Mask
(XXS size shown with EE Leak 2 Elbow)



**Figure 3: Performax Pediatric EE Total Face Mask
(XS size shown with EE Leak 1 Elbow)**

3A Front View



3B Side View

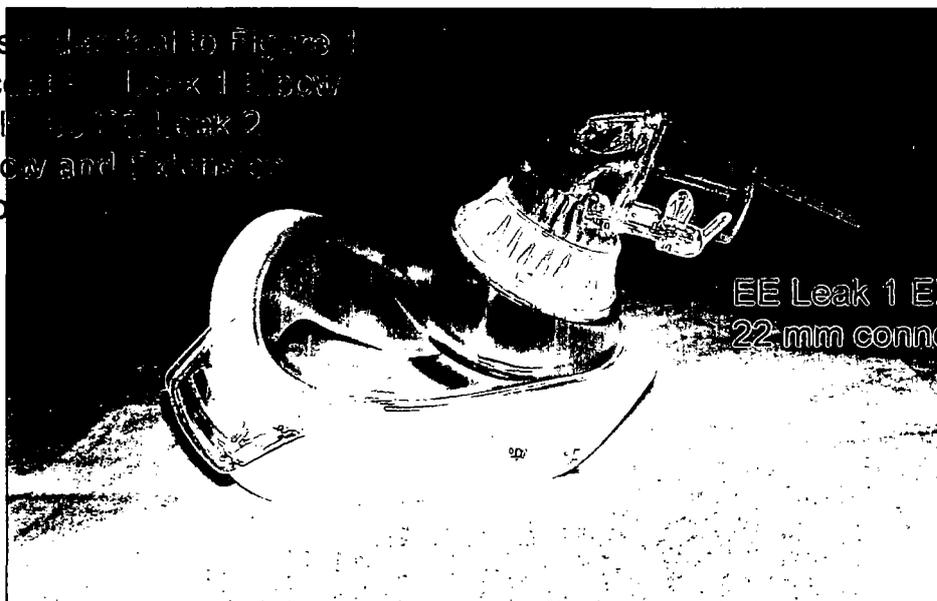


Figure 4: EE Leak 2 Elbow (Entrainment Valve Elbow with Integrated Exhalation)

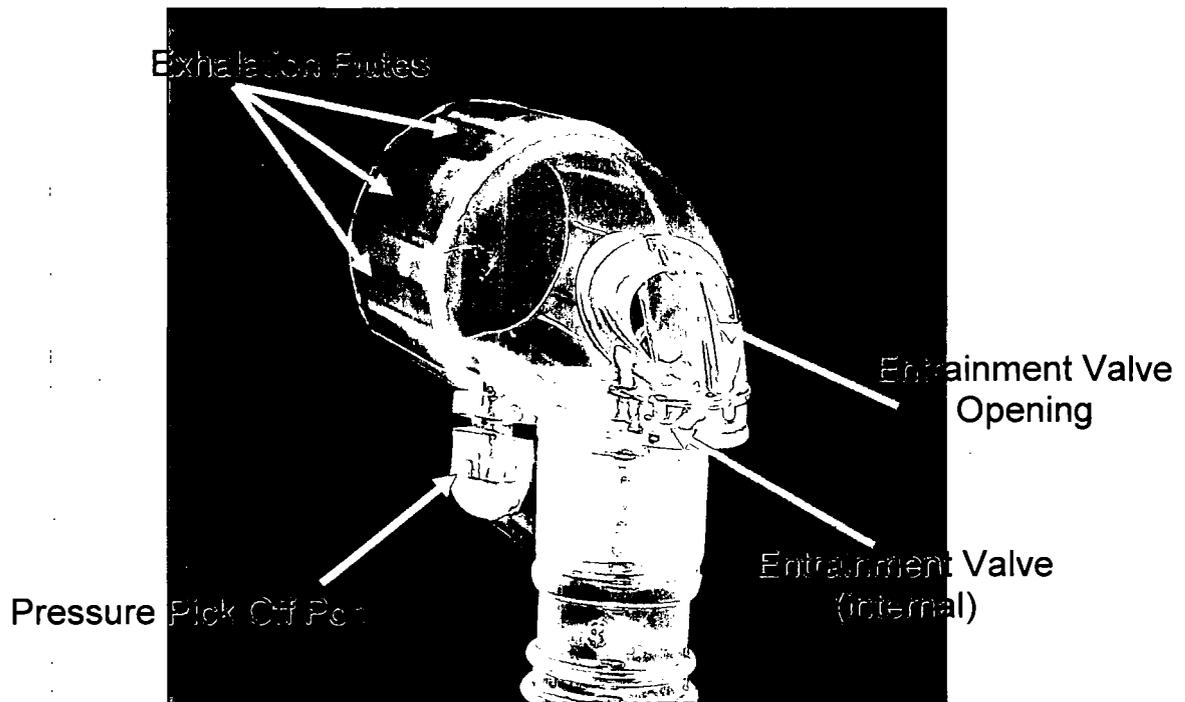


Figure 5: EE Leak 1 Elbow (Entrainment Valve Elbow without Integrated Exhalation)

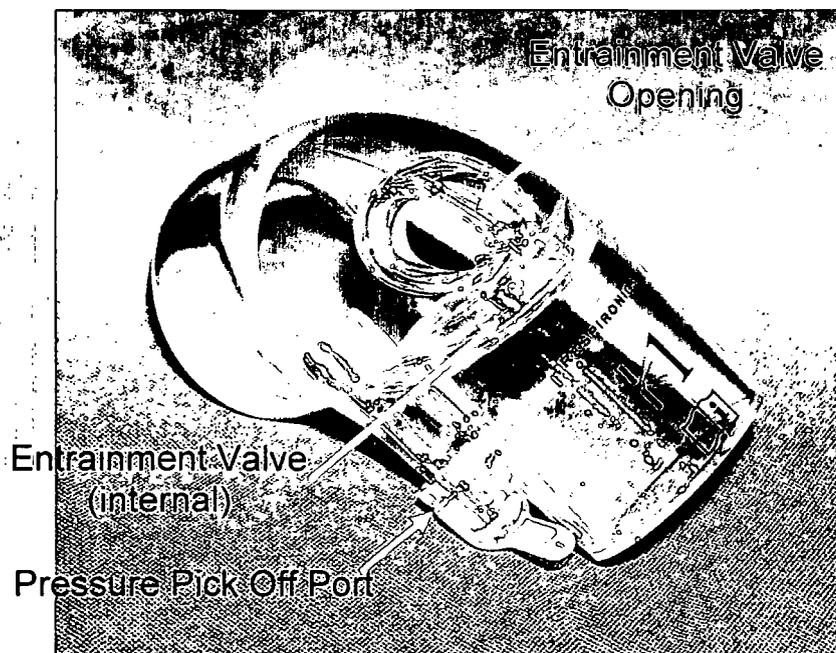
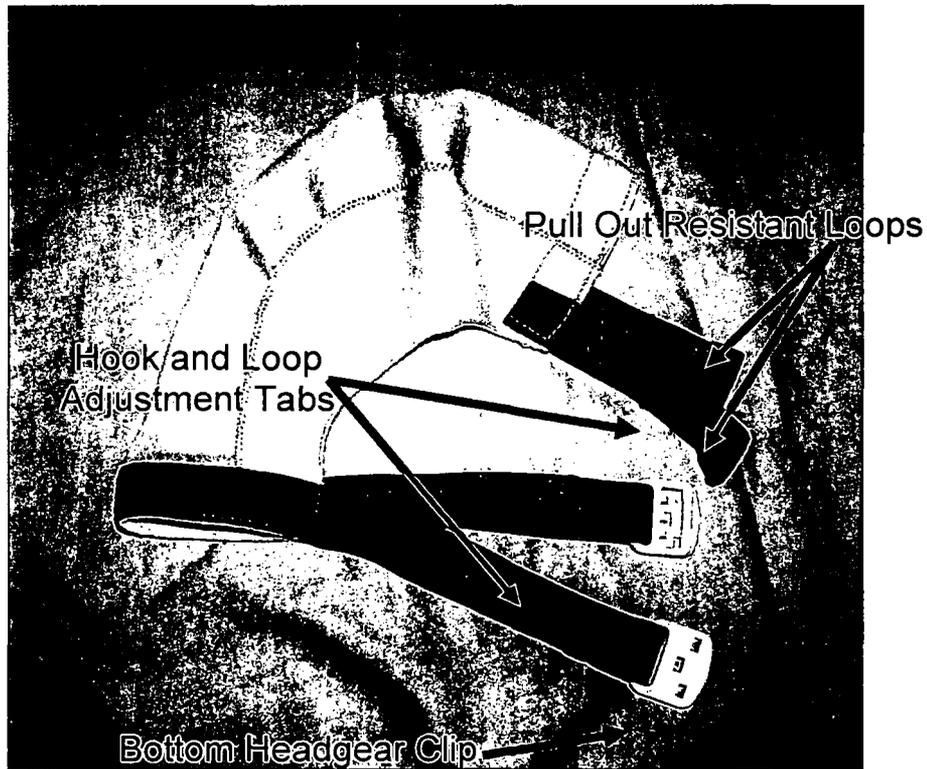


Figure 6: Bonnet Headgear



(End of Tab.)

TAB 13
PRODUCT LABELING

Draft versions of the Product Labeling for the Respironics Performax Pediatric EE Total Face Mask are included in this section. New promotional literature for the mask has not yet been generated. However, all claims will be consistent with those in this submission.

This section includes the following:

Tab 13A	Respironics Performax Pediatric EE Leak 1 Total Face Mask Instructions for Use
	Respironics Performax Pediatric EE Leak 2 Total Face Mask Instructions for Use
Tab 13B	Respironics Performax Pediatric Total Face Mask Disinfection Guide

(Please turn the page.)

Tab 13A
**PerforMax Pediatric EE Total Face Mask Instructions for
Use**

Intended Use

The PerforMax Pediatric Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital/institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Note: An exhalation port is not built into the mask. A separate exhalation device must be used with this mask.

Note: This mask does not contain natural rubber latex or DEHP.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Symbols



Warning or Caution



Note



Tip



Does Not Contain Natural Rubber Latex



Leak Symbol and Value

Warnings

- Patients using this mask must remain under constant supervision by trained medical personnel.
- This mask is not suitable for providing life support ventilation.
- Hand wash prior to use. Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.
- This mask requires a separate exhalation device.
- This mask is designed for use with CPAP or bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly. Do not block or try to seal the exhalation port. Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.
- If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Explanation of the Warning: When the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.
- At low CPAP or EPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- Some patients may experience skin redness, irritation, or discomfort. If this happens, monitor and intervene.
- Monitor and intervene if any of the following symptoms occur: Unusual chest discomfort, shortness of breath, stomach distension, belching, severe headache, blurred vision, drying of the eyes, eye pain or eye infections.
- This mask is not recommended if the patient is taking a prescription drug that may cause vomiting.
- Monitor and intervene if the patient encounters tooth, gum, or jaw soreness. Use of a mask may aggravate a patient's existing dental conditions.
- A minimum of 3cm H₂O pressure must be maintained when using this mask.
- The mask contains small parts which could result in a choking hazard.
- Attaching an exhalation device requires therapy pressure level adjustment to compensate for increased leak.
- Do not overtighten the headgear straps. Watch for signs of overtightening, such as excessive redness, bruises, sores or bulging around the edges of the mask. Loosen the headgear straps to alleviate symptoms.
- Do not block or seal off the anti-asphyxia valve.

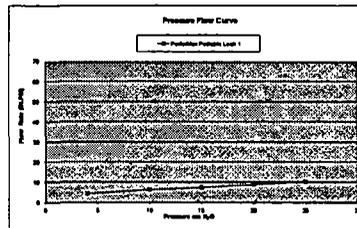
Contraindications

This mask may not be suitable for use on patients with the following conditions: glaucoma, recent eye surgery or dry eyes, impaired nictitation (blinking), hiatus hernia, impaired cardiac sphincter function, esophageal reflux, impaired cough reflex; or on patients who are not under constant, immediate observation by personnel experienced in noninvasive ventilation management.

Specifications

Warning: The technical specifications of the mask are provided to determine if it is compatible with your CPAP or bi-level therapy device. If used outside these specifications, or if used with incompatible devices, the mask may be uncomfortable, the seal of the mask may not be effective, optimum therapy may not be achieved, and leak or variation in the rate of leak may affect device function.

Pressure Flow Curve



Resistance with Anti-Asphyxia Valve Closed to Atmosphere

Drop in Pressure at

	50 SLPM	100 SLPM
All sizes	0.4 cm H ₂ O	1.0 cm H ₂ O

Inspiratory and Expiratory Resistance with Anti-Asphyxia Valve Open to Atmosphere

Inspiratory Resistance	1.5 cm H ₂ O
Expiratory Resistance	0.8 cm H ₂ O

Deadspace

XXS	283 ml
XS	311 ml

Disposal

Dispose of in accordance with local regulations.

Storage Conditions

Temperature: -4° to 140° F (-20° to +60° C)
Relative Humidity: 15% to 95% non-condensing

RESPIRONICS

DRAFT Instructions for Use

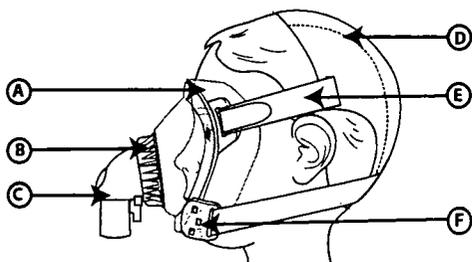
PerforMax Pediatric EE Leak 1 Total Face Mask



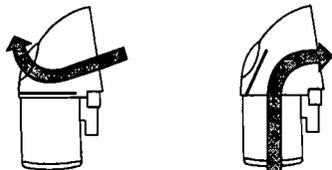
Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668 USA



Features



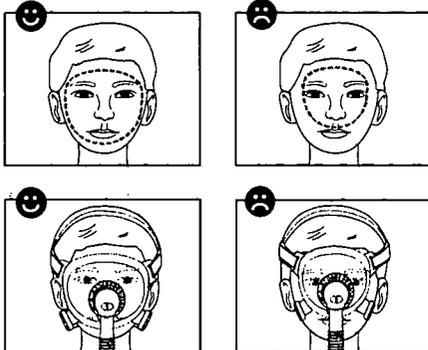
- A Mask Cushion
- B Faceplate Hub
- C Entrainment Elbow with Anti-Asphyxia Valve (Do not block.)
- D Bonnet
- E Top Headgear Straps
- F Bottom Headgear Clips



2a

2b

Sizing the Mask



Verify the Anti-Asphyxia Valve

The anti-asphyxia valve consists of an air inlet and a flapper. With the airflow turned off, verify that the elbow with the flapper is lying flat (2a) so that room air can flow in and out through the air inlet. Next, with the airflow on, the flapper should now cover the air inlet and air from the CPAP or bi-level device should flow into the mask (2b). If the flapper does not close or does not function properly, replace.

Warning: Do not block or seal the anti-asphyxia valve.

Before Use Read and Understand the Instructions Completely

- Hand wash the mask.
- Wash the patient's face. Do not use moisturizer/lotion on your hands or the patient's face.
- Inspect the mask and replace it if the cushion has hardened or is torn, or if any parts are broken.
- Verify that the therapy device, i.e., ventilator, including the alarms and safety systems, has been validated prior to use.
- Verify therapy device pressure(s).

Pre-cleaning Instructions

Hand wash the mask before first use.

1. Hand wash mask in warm water with liquid dishwashing detergent or wipe with a 70% v/v isopropyl alcohol swab.
2. Rinse thoroughly. Air dry completely before use. Make sure the mask is dry before use.

Caution: Do not use bleach, cleaning solutions containing bleach, or cleaning solutions containing conditioners or moisturizers.

Caution: Any deviation from these instructions may impact the performance of the product.

Caution: Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.

Institutional Disinfection

For multi-patient use in the hospital/institutional environment, use the Disinfection Guide to reprocess the mask between patients. These instructions can be obtained by visiting us online at www.philips.com/NIVmasks or by contacting customer service at 1-800-345-6443 or at 1-724-387-4000.

Leak Symbol and Port Settings

Some ventilators may incorporate the use of a leak symbol and value in the mask selection setup procedures. The leak characteristics of this mask is leak symbol (L1). The leak symbol and value represents the intentional leak characteristics of the interface. On ventilators equipped with a Mask Selection control, enter the leak symbol value (L1) that corresponds with the leak symbol value on the mask.

Comfort Tips

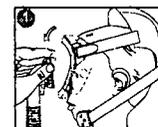
- The most common mistake is overtightening the headgear. The headgear should fit loose and comfortable. If the patient's skin bulges around the mask or if you see red marks on the patient's face, loosen the headgear.
- Adjust the top headgear straps to reduce leaks at the forehead and temples.
- Adjust the bottom headgear straps to reduce leaks at the sides of the patient's face.

Perform Max Interchangeable Leak 1 and Leak 2 Elbows

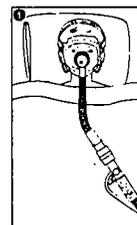
This mask may use the EE Leak 1 and EE Leak 2 elbows interchangeably. The clear EE Leak 1 elbow with an anti-asphyxia valve does not have built in exhalation. A separate exhalation device must be used with the EE Leak 1 elbow. The amber EE Leak 2 elbow with an anti-asphyxia valve includes exhalation. Refer to 2 of the Disassembly and Assembly of the Mask to change the elbow on the mask.

Achieving the Right Fit

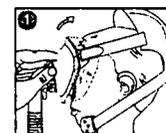
Applying the mask:



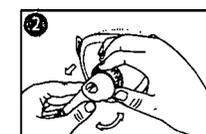
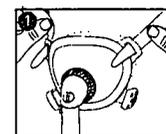
Using the mask:



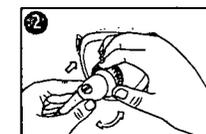
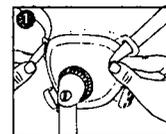
Removing the Mask:



Disassembly of the Mask:



Assembly of the Mask:



Intended Use

The PerforMax Pediatric Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital/institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

⊖ **Note:** An exhalation port is built into the mask so a separate exhalation port is not required.

⊖ **Note:** This mask does not contain natural rubber latex or DEHP.

⚠ **Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician.

Symbols



Warning or Caution



Note



Tip



Does Not Contain Natural Rubber Latex



Leak Symbol and Value

Warnings

- Patients using this mask must remain under constant supervision by trained medical personnel.
- This mask is not suitable for providing life support ventilation.
- Hand wash prior to use. Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.
- This mask is designed for use with CPAP or bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly. Do not block or try to seal the exhalation port. Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.
- If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Explanation of the Warning: When the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.
- At low CPAP or EPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- Some patients may experience skin redness, irritation, or discomfort. If this happens, monitor and intervene.
- Monitor and intervene if any of the following symptoms occur: Unusual chest discomfort, shortness of breath, stomach distension, belching, severe headache, blurred vision, drying of the eyes, eye pain or eye infections.
- This mask is not recommended if the patient is taking a prescription drug that may cause vomiting.
- Monitor and intervene if the patient encounters tooth, gum, or jaw soreness. Use of a mask may aggravate a patient's existing dental conditions.
- A minimum of 3cm H₂O pressure must be maintained when using this mask.
- The mask contains small parts which could result in a choking hazard.
- Attaching an exhalation device requires therapy pressure level adjustment to compensate for increased leak.
- Do not overtighten the headgear straps. Watch for signs of overtightening, such as excessive redness, bruises, sores or bulging skin around the edges of the mask. Loosen the headgear straps to alleviate symptoms.
- Do not block or seal off the anti-asphyxia valve.

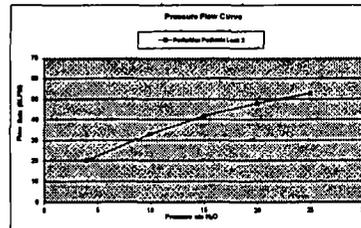
Contraindications

This mask may not be suitable for use on patients with the following conditions: glaucoma, recent eye surgery or dry eyes, impaired nictitation (blinking), hiatus hernia, impaired cardiac sphincter function, esophageal reflux, impaired cough reflex; or on patients who are not under constant, immediate observation by personnel experienced in noninvasive ventilation management.

Specifications

⚠ **Warning:** The technical specifications of the mask are provided to determine if it is compatible with your CPAP or bi-level therapy device. If used outside these specifications, or if used with incompatible devices, the mask may be uncomfortable, the seal of the mask may not be effective, optimum therapy may not be achieved, and leak, or variation in the rate of leak, may affect device function.

Pressure Flow Curve



Resistance with Anti-Asphyxia Valve Closed to Atmosphere Drop in Pressure at

	50 SLPM	100 SLPM
All sizes	0.7 cm H ₂ O	2.1 cm H ₂ O

Inspiratory and Expiratory Resistance with Anti-Asphyxia Valve Open to Atmosphere

Inspiratory Resistance	1.2 cm H ₂ O
Expiratory Resistance	0.7 cm H ₂ O

Deadspace

XXS	255 mL
XS	284 mL

Disposal

Dispose of in accordance with local regulations.

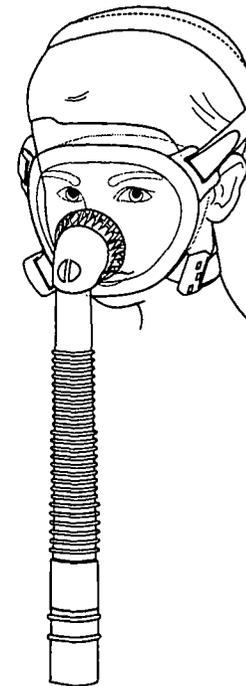
Storage Conditions

Temperature: -4° to 140° F (-20° to +60° C)
Relative Humidity: 15% to 95% non-condensing

RESPIRONICS

DRAFT Instructions for Use

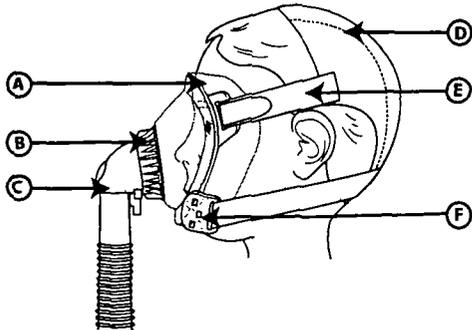
PerforMax Pediatric EE Leak 2 Total Face Mask



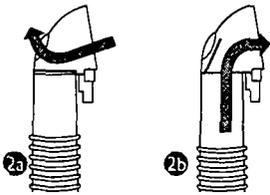
Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668 USA



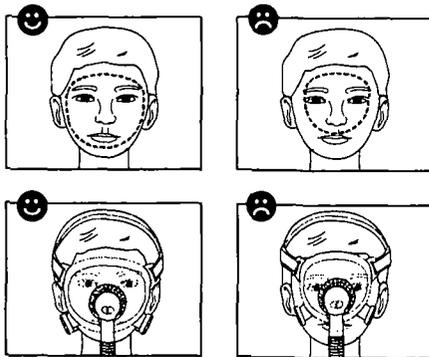
Features



- A Mask Cushion
- B Faceplate Hub
- C Entrainment Elbow with Anti-Asphyxia Valve and Exhalation (Do not block)
- D Bonnet
- E Top Headgear Straps
- F Bottom Headgear Clips



Sizing the Mask



Verify the Anti-Asphyxia Valve

The anti-asphyxia valve consists of an air inlet and a flapper. With the airflow turned off, verify that the elbow with the flapper is lying flat ^{2a} so that room air can flow in and out through the air inlet. Next, with the airflow on, the flapper should now cover the air inlet and air from the CPAP or bi-level device should flow into the mask. ^{2b} If the flapper does not close or does not function properly, replace.

Warning: Do not block or seal the anti-asphyxia valve.

Before Use Read and Understand the Instructions Completely

- Hand wash the mask.
- Wash the patient's face. Do not use moisturizer/lotion on your hands or the patient's face.
- Inspect the mask and replace it if the cushion has hardened or is torn, or if any parts are broken.
- Verify that the therapy device, i.e., ventilator, including the alarms and safety systems, has been validated prior to use.
- Verify therapy device pressure(s).

Pre-cleaning Instructions

Hand wash the mask before first use.

1. Hand wash mask in warm water with liquid dishwashing detergent or wipe with a 70% v/v isopropyl alcohol swab.
2. Rinse thoroughly. Air dry completely before use. Make sure the mask is dry before use.

Caution: Do not use bleach, cleaning solutions containing bleach, or cleaning solutions containing conditioners or moisturizers.

Caution: Any deviation from these instructions may impact the performance of the product.

Caution: Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.

Institutional Disinfection

For multi-patient use in the hospital/institutional environment, use the Disinfection Guide to reprocess the mask between patients. These instructions can be obtained by visiting us online at www.philips.com/NIVmasks or by contacting customer service at 1-800-345-6443 or at 1-724-387-4000.

Leak Symbol and Port Settings

Some ventilators may incorporate the use of a leak symbol and value in the mask selection setup procedures. The leak characteristics of this mask is leak symbol ² (2). The leak symbol and value represents the intentional leak characteristics of the interface. On ventilators equipped with a Mask Selection control enter the leak symbol value ² (2) that corresponds with the leak symbol value on the mask.

Comfort Tips

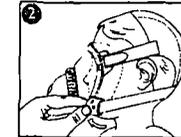
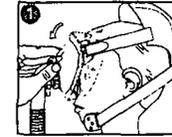
- The most common mistake is overtightening the headgear. The headgear should fit loose and comfortable. If the patient's skin bulges around the mask or if you see red marks on the patient's face, loosen the headgear.
- Adjust the top headgear straps to reduce leaks at the forehead and temples.
- Adjust the bottom headgear straps to reduce leaks at the sides of the patient's mouth.

PerforMax Interchangeable Leak 1 and Leak 2 Elbows

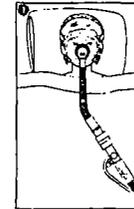
This mask may use the EE Leak 1 and EE Leak 2 elbows interchangeably. The clear EE Leak 1 elbow with an anti-asphyxia valve does not have built in exhalation. A separate exhalation device must be used with the EE Leak 1 elbow. The amber EE Leak 2 elbow with an anti-asphyxia valve includes exhalation. Refer to ² of the Disassembly and Assembly of the Mask to change the elbow on the mask.

Achieving the Right Fit

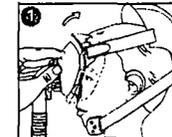
Applying the mask:



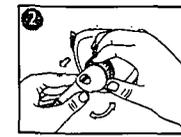
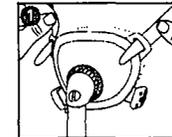
Using the Mask:



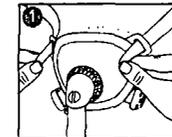
Removing the Mask:



Disassembly of the Mask:



Assembly of the Mask:



Tab 13B
PerforMax Pediatric Total Face Mask Disinfection Guide

RESPIRONICS

Disinfection Guide for Professional Use Only

The following disinfection methods are validated for Respiroics multi-patient use masks in the hospital/institutional environment.

High-Level Disinfection

Product	Thermal	Chemical	Max Cycles	Notes
PerforMax Pediatric	90° C for 1 minute	Cidex	10	The EE Leak 2 elbow with tubing and EE Leak 1 elbow should not be disinfected.

1 Pre-Treatment Cleaning

⚠ Caution

Follow all instructions from the manufacturer of the pre-treatment products. Any deviation from these instructions may impact the performance of the product. Review all applicable instructions for additional warnings and cautions.

- Disassemble the mask according to the **Instructions for Use** included with the product.
- Clean the mask using a soft bristle brush to adequately remove adhering substances from each component while soaking in a commercially available, anionic detergent (Examples: MEDIZIME LF). Extra attention should be given to the crevices and cavities during cleaning.
- If compatible with the manufacturer's instructions, the detergent may be applied within the washer/disinfection cycle.
- Rinse the mask with 5 liters of water and air dry out of direct sunlight.

2 High-Level Disinfection

The recommended disinfection methods are identified by mask product (above chart) and approved (⊙) for use on the mask and/or mask parts. Review the notes (⊖) section for exceptions or deviations.

⚠ Caution

Follow all instructions from the manufacturer of the disinfection products. Any deviation from the manufacturer's instructions or use of agents other than those listed in this guide may impact the performance or durability of the product. Review all applicable instructions for additional warnings and cautions.

⚠ Warnings

Before Disinfection

- The fabric materials (eg: headgear, straps) cannot be disinfected using the methods listed. The fabric materials must be replaced before multi-patient use.
- Masks with port caps: Open or remove the port cap prior to disinfecting the mask.

After Disinfection

- Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc.)
- Rinse thoroughly with water and air dry out of direct sunlight. Make sure the mask is dry before use.
- Verify the entrainment valve functions correctly, as outlined in the **Instructions for Use** included with the product.

Note

- After disinfection, discoloration and a slight odor is normal.

Chemical Agent Active Ingredients

Cidex - 2.4% glutaraldehyde

Contact Respiroics

Visit us on-line at www.philips.com/NIVmasks to download copies of the Disinfection Guide or contact customer service.

Respiroics: 1-800-345-6443 (USA or Canada only) or 724-387-4000

Respiroics Deutschland: +49 (0) 8152 93060

PerforMax is a trademark of Respiroics Inc.

CIDEX is a trademark of Johnson & Johnson. MEDIZIME LF is a trademark of Medical Chemical Corporation.

Respiroics Inc.

1001 Murry Ridge Lane
Murrysville, PA 15668 USA



REF 1093809

Rev02
ALC 02/17/2012
000074

TAB 14
STERILIZATION AND SHELF LIFE

The efficacy of the disinfection process on the components that are in the air pathway was evaluated for the PerforMax Pediatric EE Total Face Mask, intended for multi-patient use, using the guidance provided in:

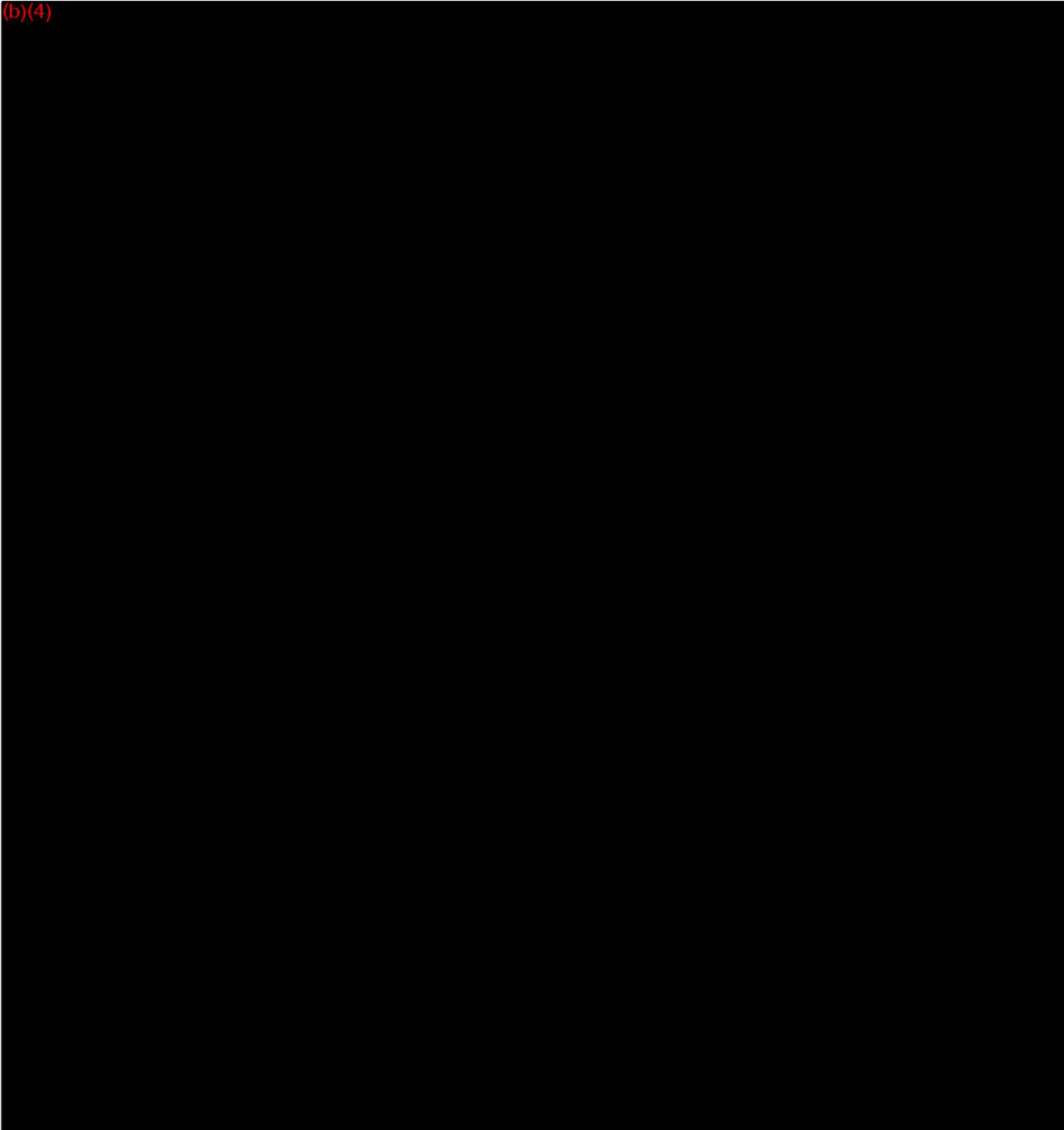
- AAMI TIR No.12-2004, Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for the Device Manufacturer, 23 December 2004
- AAMI TIR No. 30-2003, A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices, 8 October 2003
- ASTM E1837-96 (Re-approved 2002), Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test), Oct. 10, 1996
- ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

(b)(4)

A disinfection effectiveness study was performed using approved Respironics Quality System Procedure (QSP) protocols for the PerforMax Total Face Mask (K072592) using (b)(4). The PerforMax Pediatric EE Total Face Mask did not require an additional cleaning efficacy study as the mating interfaces are unchanged from the predicate. The elbow is a single use component and is not to be disinfected per the disinfection instructions.

(b)(4)

(b)(4)



The following supporting documents are provided:

(b)(4)	(b)(4)
--------	--------

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

(Please turn the page.)

TAB 15
BIOCOMPATIBILITY ASSESSMENT

The skin contacting and gas pathway materials have been evaluated in accordance with the guidance provided in ISO-10993-1. A declaration of conformity to ISO-10993-1 is provided in Tab 9 of this submittal.

The biocompatibility information provided in this submission includes the following:

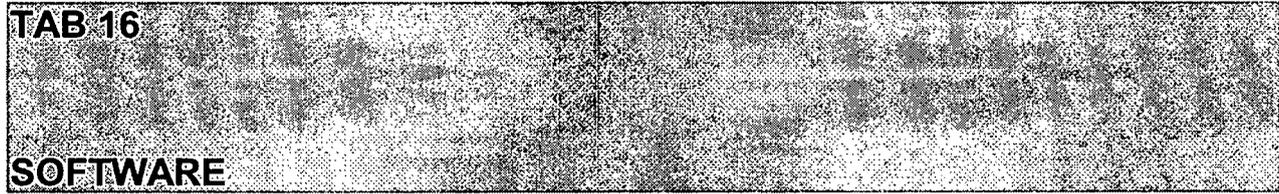
Tab 9A	Declaration of Conformity to ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process <i>Includes summary materials table and exploded assembly diagrams</i>
	FORM FDA 3654 Standards Data Report for 510(k)s – ISO 10993-1:2009
	Summary Report for ISO 10993-1:2009
Tab 15A	Biocompatibility Report (b)(4)Testing
Tab 15B	Biocompatibility Report (b)(4)Testing
Tab 15C	Biocompatibility Report (b)(4)Testing

(Please turn the page.)

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PERFORMAX PEDIATRIC EE TOTAL FACE MASK – TRADITIONAL 510(K)

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FDA CDRH DMC
 FEB 24 2012
 Received



The design of the Respironics PerforMax Pediatric EE Total Face Mask does not include any software. This section is not applicable.

(End of Tab.)

TAB 17

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The design of the Respironics PerforMax Pediatric EE Total Face Mask does not include any electro-mechanical mechanisms. This section is not applicable for this submittal.

(End of Tab.)



No animal testing was performed. This section is not applicable.

(End of Tab.)

TAB 20

PERFORMANCE TESTING - CLINICAL

The design of the PerforMax Pediatric EE Total Face Mask did not require clinical evidence to demonstrate substantial equivalence. Use of masks to deliver non-invasive positive airway pressure by devices such as CPAP or bi-level systems is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the mask, as was the case with the predicate devices.

Market analysis and clinical literature reviews indicated a need for a pediatric oro-nasal mask. The clinical study detailed in "*Outcome of paediatric domiciliary mask ventilation in neuromuscular and skeletal disease*" (Simonds, AK; Ward, S; Heather, S; Bush, A; Muntoni, F, 2000)¹, included 40 patients ranging in age from 9 months to 16 years that were non-invasively ventilated using several nasal and oro-nasal interfaces. In some cases adult medium sized nasal masks were used as face masks, depending on the age, size and facial contours of the child.

(End of Tab.)

¹ Simonds, A K, Bush, A, Heather, S, Muntoni, F, Ward, S, "*Outcome of paediatric domiciliary mask ventilation in neuromuscular and skeletal disease.*" European Respiratory Journal. September, 2000. Vol: 16 Issue: 3 Pages: 476-481.



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 Respironics, Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Feb 21, 2012
3. ADDRESS (Number, Street, State, and ZIP Code) 1001 Murry Ridge Lane Murrysville, PA 15668	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 724-387-5200 (Fax) 724-387-7490

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)

Common/Usual Name: Face Mask

Classification: Class II

Trade/Proprietary Name: PerforMax Pediatric EE Total Face Mask

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)
N/A - Not assigned

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
N/A

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) (b) (6)	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Gary Lotz (Title) Senior Manager Clinical Research
13. ADDRESS (Number, Street, State, and ZIP Code) (or person identified in Nos. 11 and 12) Home Healthcare Solutions / 286 1740 Golden Mile Highway Monroeville, PA 15146	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 724-733-5812 (Fax) 724-387-7600
15. DATE OF CERTIFICATION Feb 21, 2012	

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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

K120562 / S / V /
Public Health Service

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

May 21, 2012

RESPIRONICS, INC.
SLEEP AND HOME RESPIRATORY GROUP
365 PLUM INDUSTRIAL COURT
PITTSBURGH, PENNSYLVANIA 15239
ATTN: MICHELLE BRINKER

510k Number: K120562

Product: PERFORMAX PEDIATRIC EE TOTAL F

On Hold As of 5/18/2012

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.

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

K120562 / S1

* * * COMMUNICATION RESULT REPORT (MAY. 21. 2012 11:58AM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : MAY. 21. 2012 11:57AM
MODE OPTION

ADDRESS

RESULT PAGE

5542 MEMORY TX

917243873999

OK

2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWER

E-2) BUSY
E-4) NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 21, 2012

RESPIRONICS, INC.
SLEEP AND HOME RESPIRATORY GROUP
365 PLUM INDUSTRIAL COURT
PITTSBURGH, PENNSYLVANIA 15239
ATTN: MICHELLE BRINKER

510k Number: K120562

Product: PERFORMAX PEDIATRIC EE TOTAL F
On Hold As of 5/18/2012

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>.

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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.



COVER SHEET MEMORANDUM

From: Reviewer Name James Lee
Subject: 510(k) Number K120562/S1
To: The Record

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

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/CO-MBINATION%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)?			
For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, 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.)

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 868.5905

1

BZD

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

Additional Product Codes:

Review:

 L. Scholtz
(Branch Chief)

ARDP
(Branch Code)

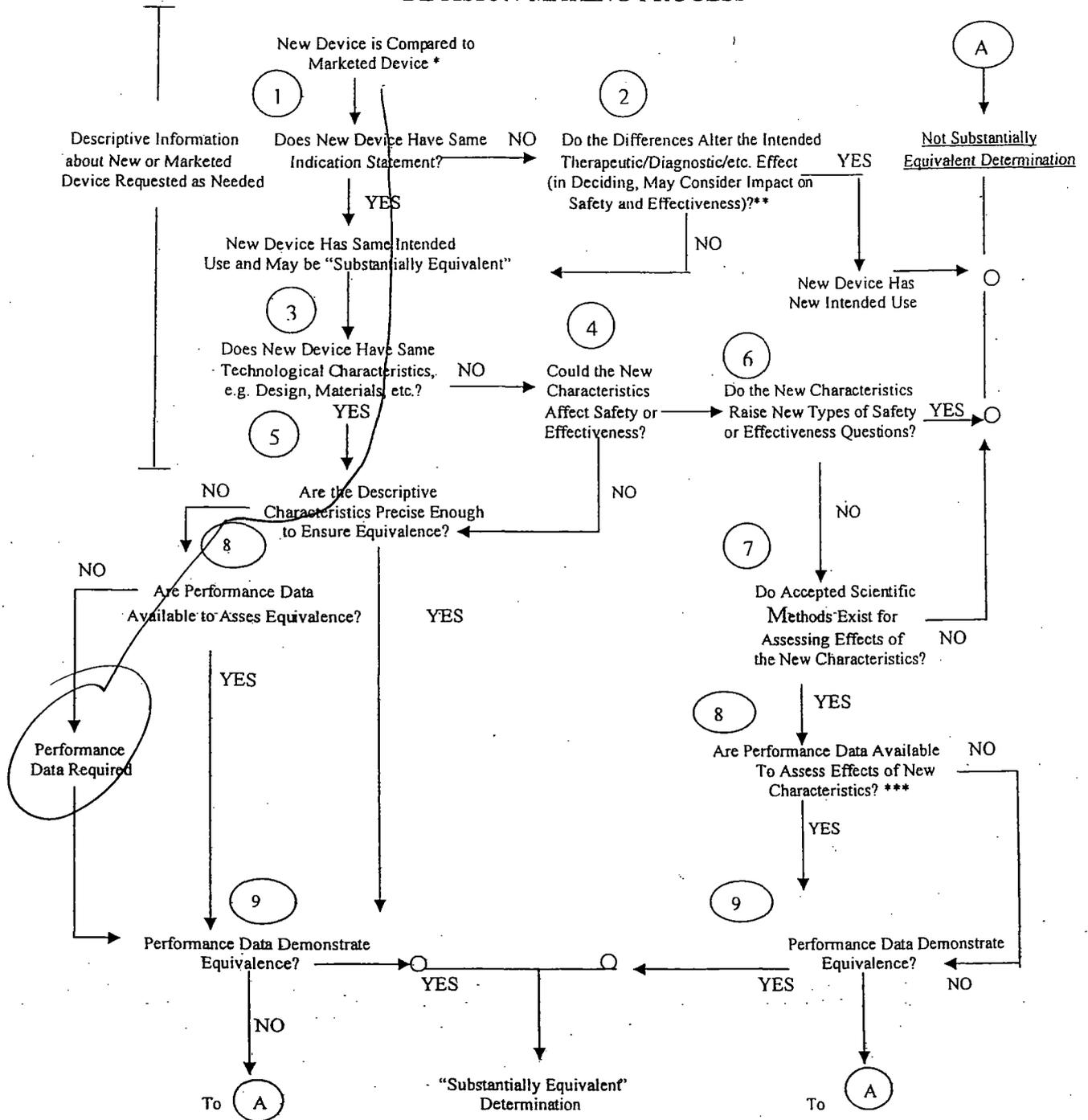
5-18-12
(Date)

Final Review:

(Division Director)

(Date)

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.



Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K120562/S001

Date: May 18, 2012
To: The Record
From: James Lee PhD
510(k) Holder: RESPIRONICS INC
Device Name: PerformMax Pediatric EE Total Face Mask
Contact: Michelle Brinker
Phone: (724) 387-4146
Fax: (724) 387-3999
Email: michelle.brinker@philips.com

Office:
Division: DAGID/ARDB

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the Respiroics PerformMax Pediatric EE Total Face Mask into interstate commerce. The PerformMax Pediatric EE Total Face Mask is a modification in design to the Respiroics PerformMax Youth EE Total Face Mask (previously cleared under K092043) and Respiroics Small Child Profile Lite Nasal Mask (previously cleared under K093416). The modifications consist of the following:

1. Updated environment to restrict to hospital/institutional use only
2. Reduced size of the faceplate and cushion
3. Modified elbow
4. Modified the mask operating pressure range, replaced unintentional leak specification with total mask leak specification, and added inspiratory and expiratory resistance specification
5. Material changes for the elbow hub, elbow body, and headgear

The modified device is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The PerformMax Pediatric EE Total Face Mask is for patients 1 year or older (> 7 kg). The mask is for multi-patient use in the hospital / institutional environment only.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC) Provided in Section 4	X		
Truthful and Accuracy Statement Provided in Section 6p	X		
510(k) Summary or 510(k) Statement Provided in Section 5	X		
Standards Form	x		

510(k) Summary

The sponsor has provided its 510(k) Summary in Section 5.

Required Elements for 510(k) Summary (21 CFR 807.92)		
	Clearly labeled "510(k) Summary"	yes
	Submitter's name, address, phone #, a contact person	yes
	Date the summary was prepared	yes
	The name of the device/trade name/common name/classification name	yes
	An identification of the legally marketed predicate	yes
	Description of the subject device	yes
	Statement of intended use	yes
Technological characters	if same, a summary of comparison of technological characters	yes
	If different, a summary of how do they compare to the predicate	
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	yes
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> - Description upon whom the device was tested, - Data obtained from the tests and especially: <ul style="list-style-type: none"> ▪ Adverse events and complications ▪ Other information for SE determination 	
	Conclusion that data demonstrate SE	
Required Elements for 510(k) Statement (21 CFR 807.93)		N/A
	Signed verbatim statement	

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)?			
Are "cleaning" instructions included for the end user?	x		

The Performax Pediatric EE Total Face Mask expands upon the existing Respiration Performax product line, which currently includes a size cleared for patients 7 years and older (> 18.2 kg).

The Performax Pediatric EE Total Face Mask consists of a (b) (4) faceplate, a silicone cushion that seals along the perimeter of the face, an elbow with an integral entrainment valve, and an

elbow hub that retains the elbow. A pressure-pick off port is located on the elbow body. The mask is secured to the head with a bonnet style headgear.

The PerforMax elbow hub allows the medical professional to use the mask with either an Entrainment Elbow (EE) Leak 2 or an Entrainment Elbow (EE) Leak 1. The EE Elbow is a simple press fit assembly into the hub of the mask.

(b) (4)

(b) (4)

The EE Leak 2 elbow has a 6" fixed 15 mm to 22 mm flexible extension tube attached. There is a 22 mm swivel connector at the end of the tubing to attach to standard 22 mm tubing used with CPAP and bi-level systems. The EE Leak 1 elbow connects directly to standard 22 mm tubing used with CPAP and bi-level systems (see Figure 3). The EE Leak 1 elbow does not include an extension tube or swivel. The PerforMax Pediatric EE Total Face Mask is available in two sizes, XS and XXS.

IV. Indications for Use

Indications for Use as provided in Section 4 of the original submission:

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bilevel system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Prescription Use has been indicated.

Predicate Indications for Use:

PerforMax Youth EE Total Face Mask (K092043) –

The Respironics BiPAP Synchrony 2 is intended to provide non-invasive ventilation for pediatric patients 7 years or older(> 40 lbs) or adult patients (> 66 lbs) with respiratory insufficiency or obstructive sleep apnea, in the hospital or home.

Small Child Profile Lite Nasal Mask (K093416) –

The Respironics Trilogy200 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy200 is intended for pediatric through adult patients weighing at least 5 kg (11 lbs.).

The device is intended to be used in home, institution/hospital, and portable applications such as wheelchairs and gurneys, and may be used for both invasive and non-invasive ventilation

(b) (4)

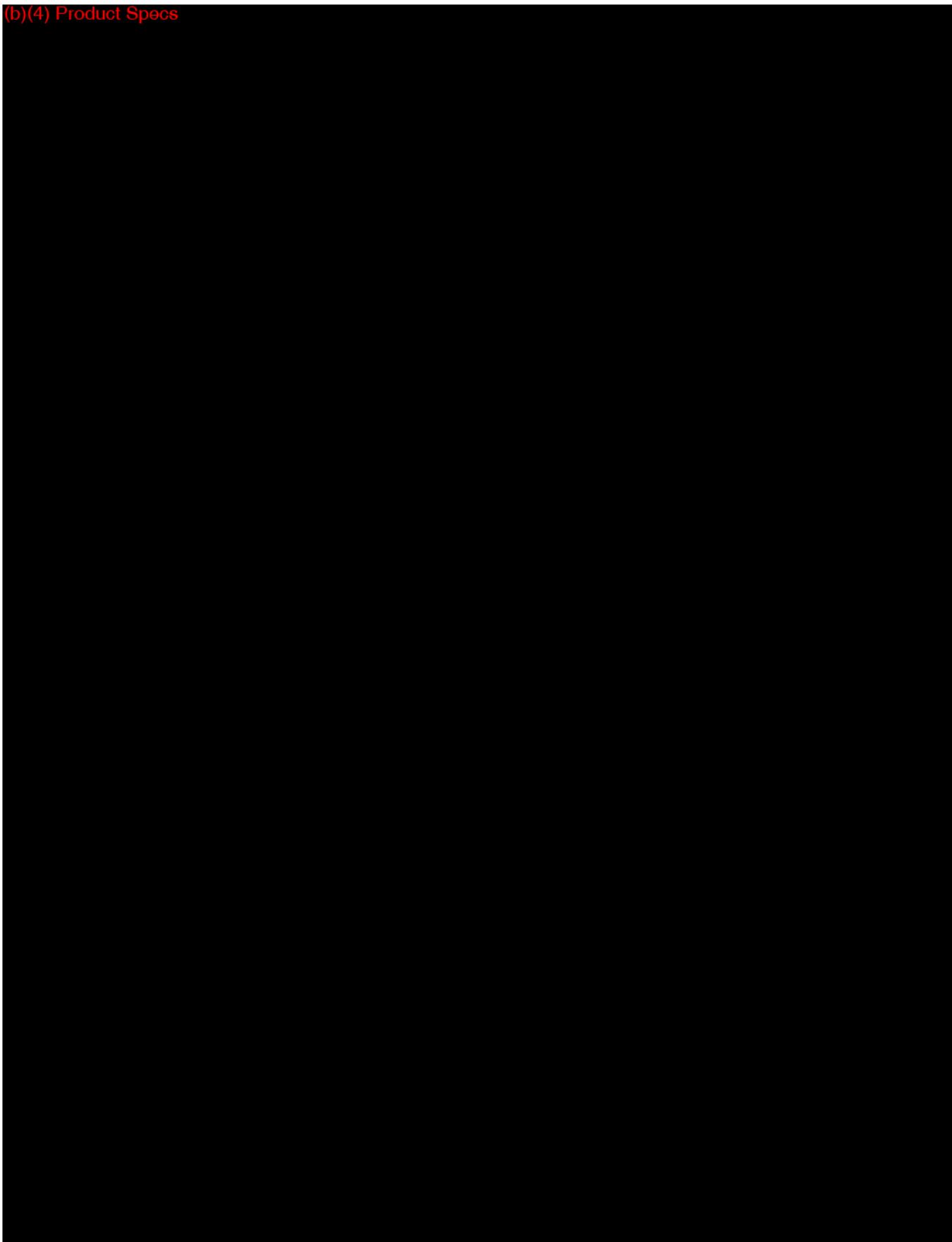
V. Predicate Device Comparison

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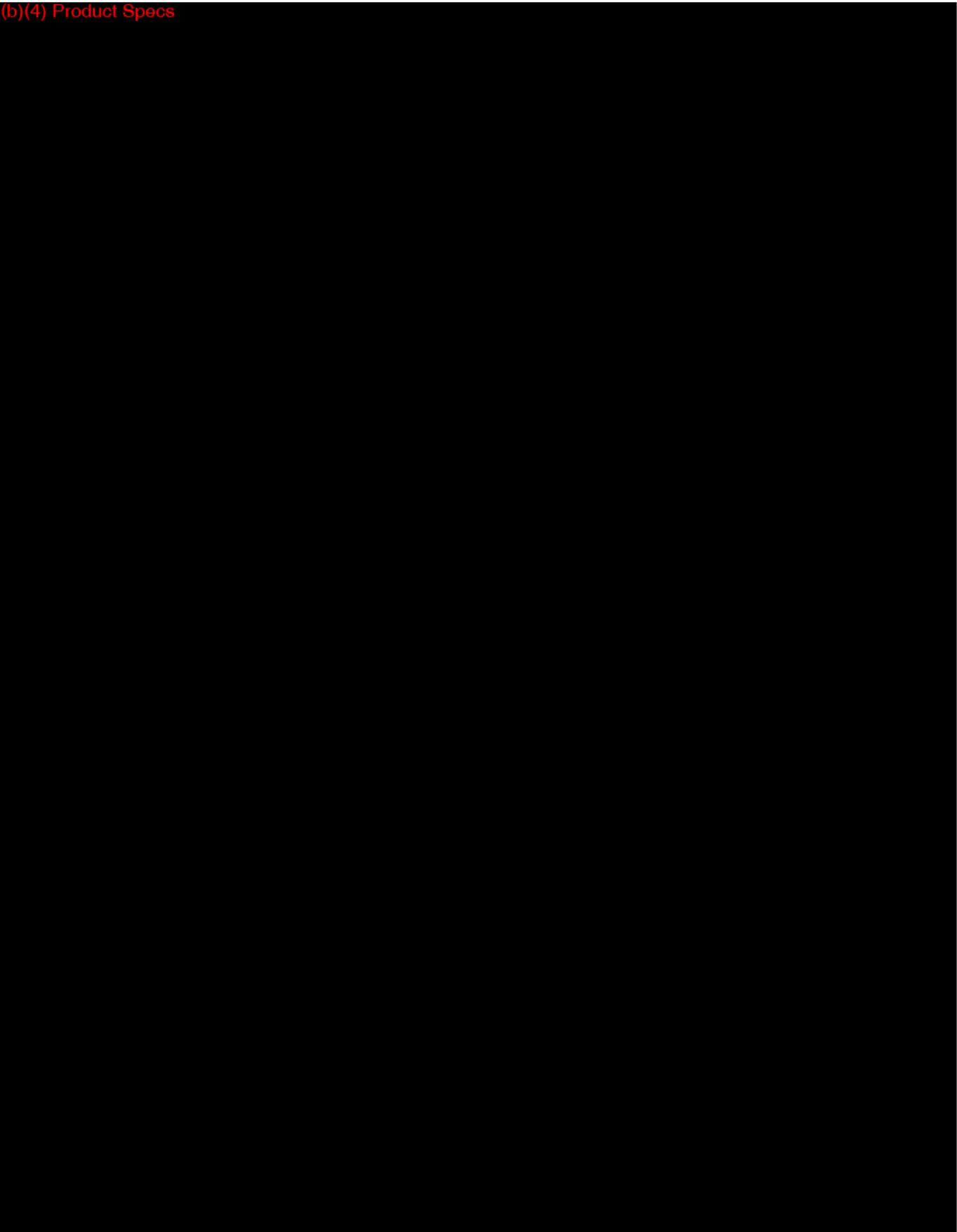
The following table compares the submitted device with the primary and secondary predicates.

	Primary Predicate Device: PerforMax Youth EE Total Face Mask Manufacturer: Respironics, Inc. 510(k) Number: K092043	Secondary Predicate Device: Small Child Profile Lite Nasal Mask Manufacturer: Respironics, Inc. 510(k) Number: K093416	Subject Device: PerforMax Pediatric EE Total Face Mask Manufacturer: Respironics, Inc. 510(k) Number: To be determined
Intended Use submitted in labeling	The PerforMax Youth EE Total Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients.	The Small Child Profile Lite Nasal Mask and Softcap are intended to provide an interface when used with CPAP or bi-level therapy.	Similar to K092043 and K093416 PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system.
<i>Patient Population</i>	7 years or older (> 18.2 kg)	1 year or older (> 7 kg)	Unchanged from K093416
<i>Environment of Use of the System</i>	Home or Hospital/institutional	Home or hospital/institutional	Hospital/institutional only
<i>Patient Usage Type</i>	Single Patient use in the home and Multi-patient use in the hospital/institutional environment	Single Patient Use	Unchanged from K092043 in the Hospital/institutional environment
<i>Product Code</i>	MNS	CBK	BZD
<i>Provided Sterile or Non-Sterile</i>	Provided clean, not sterile	Provided clean, not sterile	Unchanged from K093416/K092043
<i>Anatomical Sites</i>	Total Face Mask, covering the eyes, nose and mouth	Nasal interface, covering only the nose	Unchanged from K092043

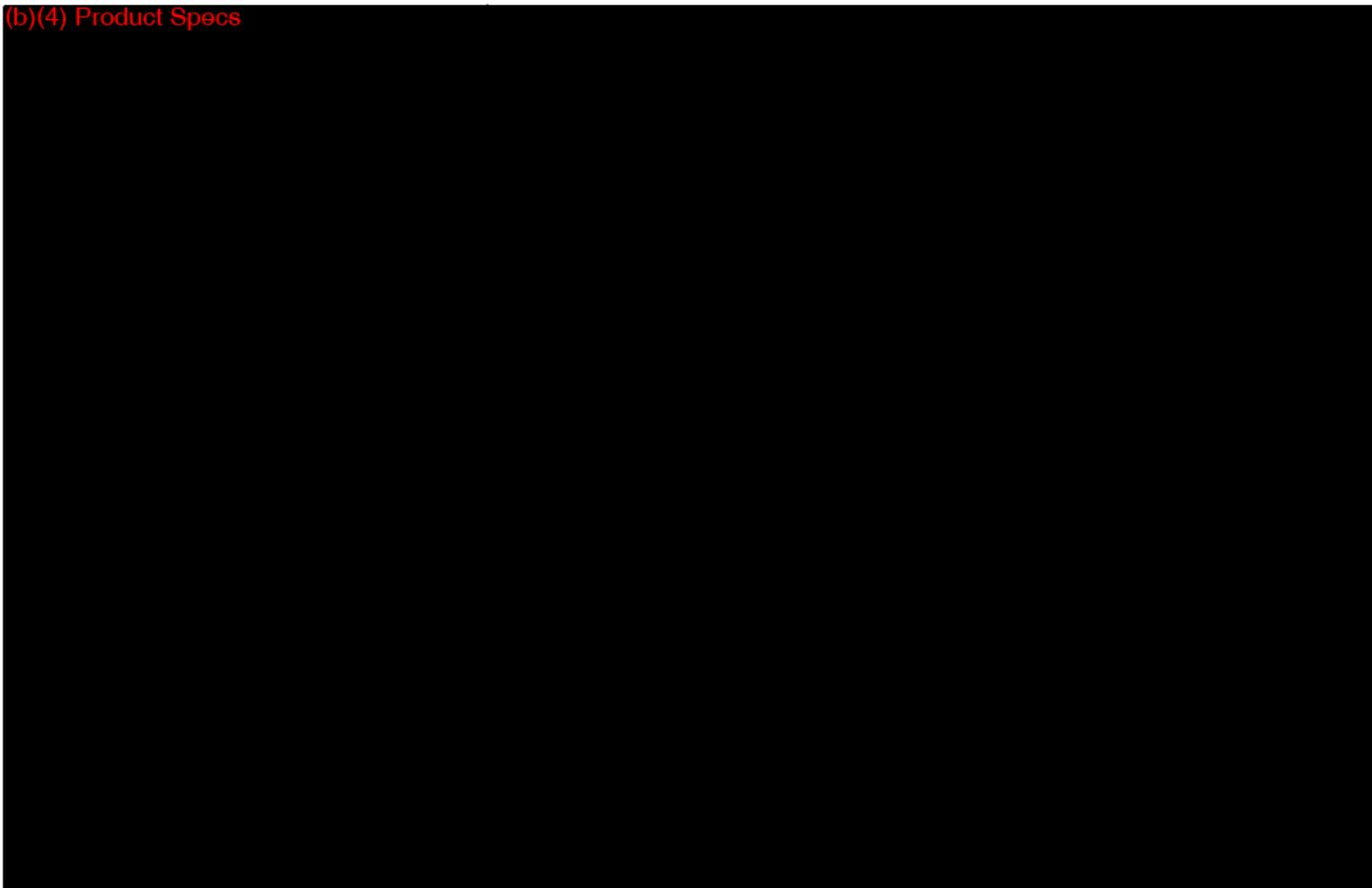
(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs



VI. Labeling

Draft labeling is provided in TAB 13 of the original submission. This section includes the instructions for use, warning and caution statements, device specifications, and reuse instructions (disinfection). The caution statement for prescription devices as required by 21 CFR 801.109: Caution: "Federal law restricts this device to sale by or on the order of a physician. Appropriate caution and warning statement related to the usage of the device are included.

VII. Sterilization/Shelf Life/Reuse

The efficacy of the disinfection process on the components that are in the air pathway was evaluated for the PerformMax Pediatric EE Total Face Mask, intended for multi-patient use, using the guidance provided in:

- AAMI TIR No.12-2004, Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for the Device Manufacturer, 23 December 2004
- AAMI TIR No. 30-2003, A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices, 8 October 2003

- ASTM E1837-96 (Re-approved 2002), Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test), Oct. 10, 1996
- ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

VIII. Biocompatibility

A skin contacting and gas pathway materials have been evaluated in accordance with the guidance provided in ISO-10993-1. A declaration of conformity to ISO-10993-1 is provided in Tab 9 of the original submission.

Tab 9A	Declaration of Conformity to ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process <i>Includes summary materials table and exploded assembly diagrams</i> FORM FDA 3654 Standards Data Report for 510(k)s – ISO 10993-1:2009 Summary Report for ISO 10993-1:2009
Tab 15A	Biocompatibility Report (b) (4)
Tab 15B	Biocompatibility Report (b)(4)
Tab 15C	Biocompatibility Report (b)(4)

IX. Software

This device has no software, this section is not applicable.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The device has not electrical or mechanical systems, this section is not applicable.

XI. Performance Testing – Bench

The following is a summary of the bench testing that was performed on the PerforMax Pediatric EE Total Face Mask.

(b)(4)

[Redacted content]

(b)(4)

[Redacted]

Environmental Testing

Per the guidance in the FDA Reviewer Guidance for Premarket Notification Submissions, November 1993, testing will be performed to demonstrate safety and effectiveness of the performance characteristics of the device in the intended environment of use and post-storage conditioning. The Intent to Declare Conformance is provided in Tab 9C and test matrix per Appendix A of FDA Reviewer Guidance for Premarket Notification Submissions, November 1993, is provided in Tab 18B.

Risk Assessment

An initial hazards assessment was performed for the PerforMax Pediatric EE Total Face Mask. The assessment analyzed the use situation, the sequence of events, and harm. An initial risk level of the harm was established based on the initial severity and probability classifications (as defined in the risk management plan in Tab 18C).

XII. Performance Testing – Animal

N/A Animal testing not needed to determine substantial equivalence.

XIII. Performance Testing – Clinical

N/A Clinical testing was not submitted to determine substantial equivalence. Submission only has a reference to a clinical study performed in 2000.

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?		x If YES = Stop NSE
3. Same Technological Characteristics?		x If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		x 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?	x	If YES = Stop NSE
7. Accepted Scientific Methods Exist?	x	If NO = Stop NSE
8. Performance Data Available?	x	If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

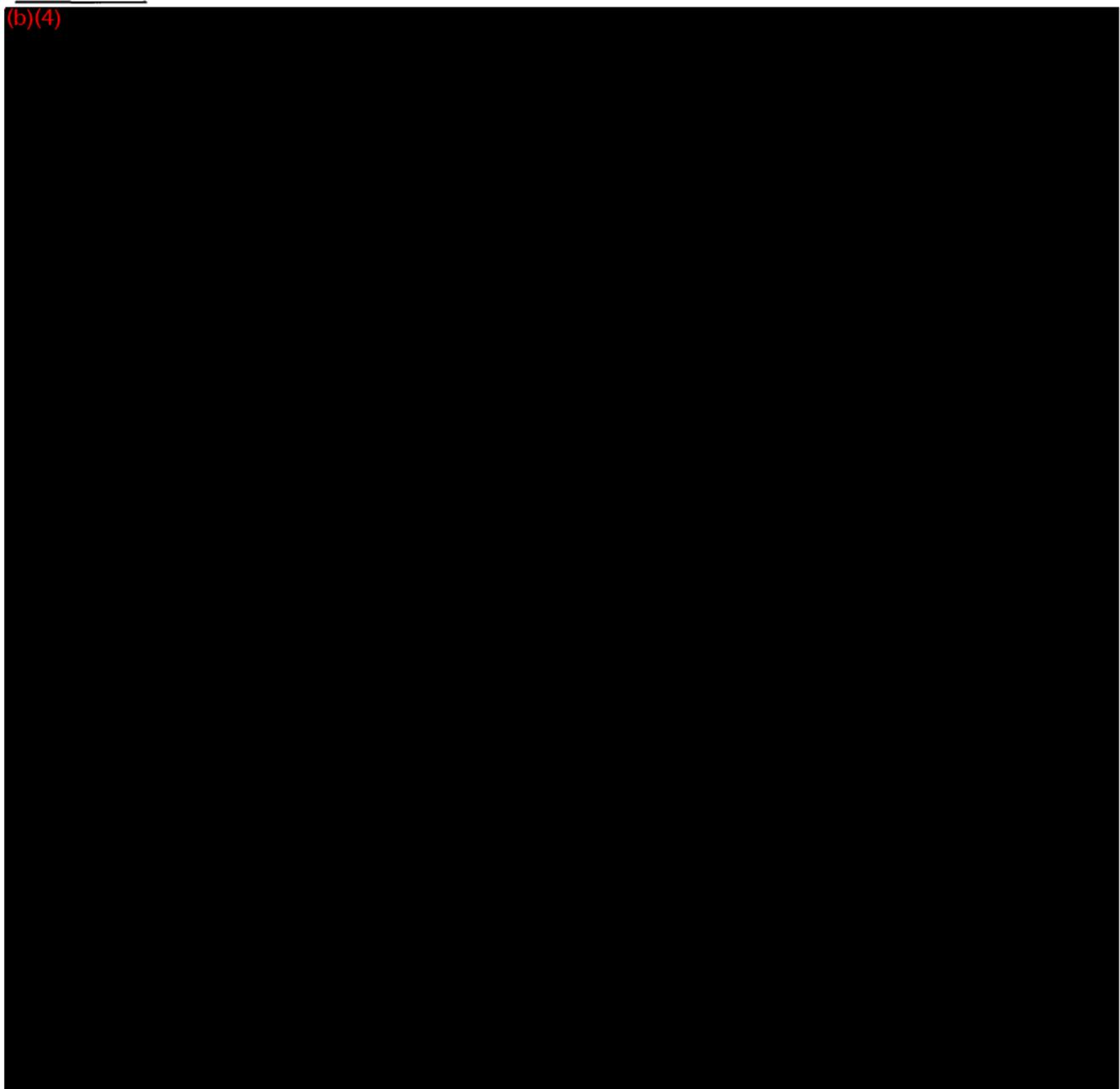
Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. 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:
Additional information regarding the verification and validation activities is needed in order to determine substantial equivalence.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not 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:

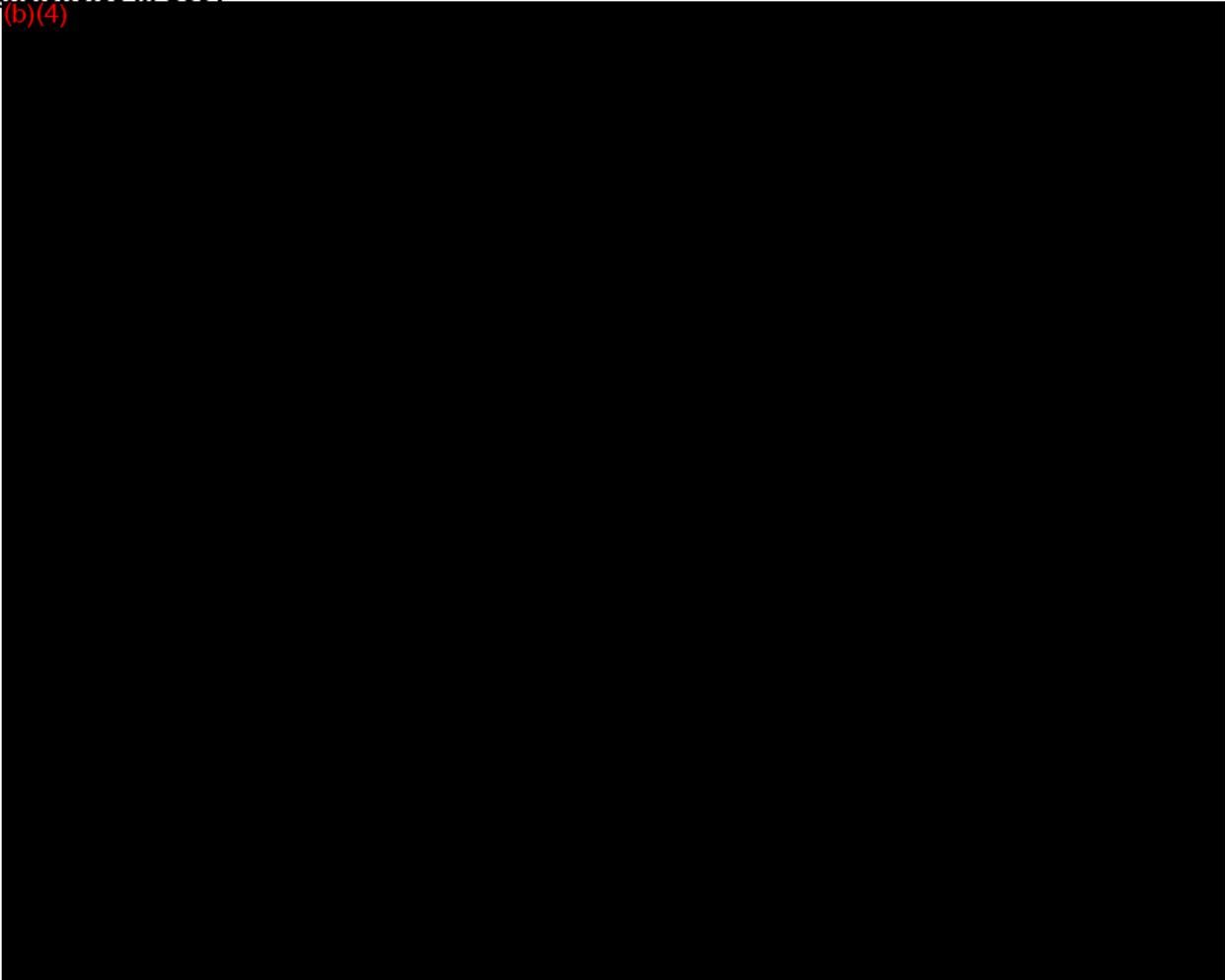
XV. Deficiencies

(b)(4)



Deficiencies in S001

(b)(4)



XVI. Contact History

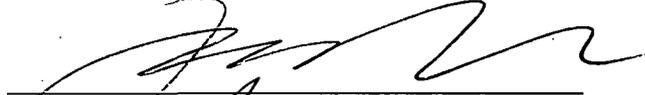
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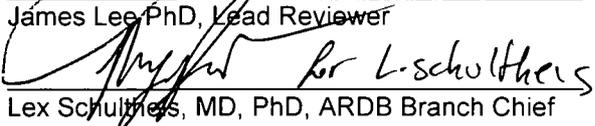


XVII. Recommendation

I recommend that the file be placed on hold pending the receipt of additional information.

Regulation Number: 21 CFR 868.5905
Regulation Name: Nasal Mask
Regulatory Class: Class II
Product Code: BZD



James Lee PhD, Lead Reviewer


Lex Schultheis, MD, PhD, ARDB Branch Chief

5-18-12
Date
5-18-12
Date



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

April 04, 2012

RESPIRONICS, INC.
SLEEP AND HOME RESPIRATORY GROUP
365 PLUM INDUSTRIAL COURT
PITTSBURGH, PENNSYLVANIA 15239
ATTN: MICHELLE BRINKER

510k Number: K120562

Product: PERFORMAX PEDIATRIC EE TOTAL F

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Wednesday, April 04, 2012 12:09 PM
To: 'michelle.brinker@philips.com'
Subject: Ack Letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-5002

April 04, 2012
 BRINKER
 MICHELLE
 RESPIRONICS, INC.
 SLEEP AND HOME RESPIRATORY GROUP
 365 PLUM INDUSTRIAL COURT
 PITTSBURGH, PENNSYLVANIA 15239
 ATTN: MICHELLE BRINKER

510k Number: K120562

Product: PERFORMAX PEDIATRIC EE TOTAL F

The additional information you have submitted has been received.

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

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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

4/4/2012



Grayson, Giovanna *

From: Microsoft Outlook
To: 'michelle.brinker@philips.com'
Sent: Wednesday, April 04, 2012 12:09 PM
Subject: Relayed: Ack Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'michelle.brinker@philips.com'

Subject: Ack Letter

Sent by Microsoft Exchange Server 2007

RESPIRONICS

K120562/S1

April 3, 2012

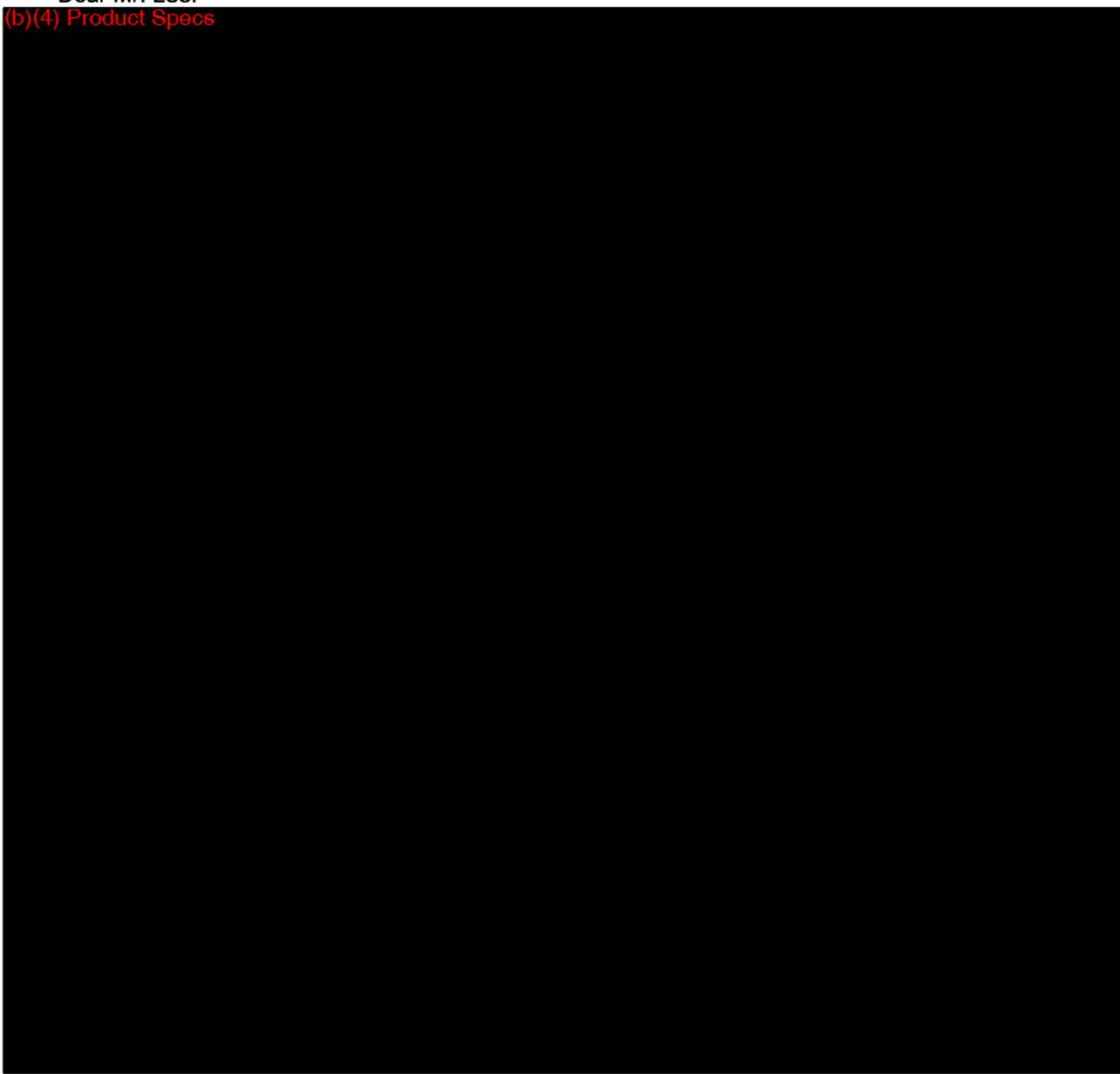
ATTN: Mr. James Lee, Ph.D., M.S.E.
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

APR 04 2012

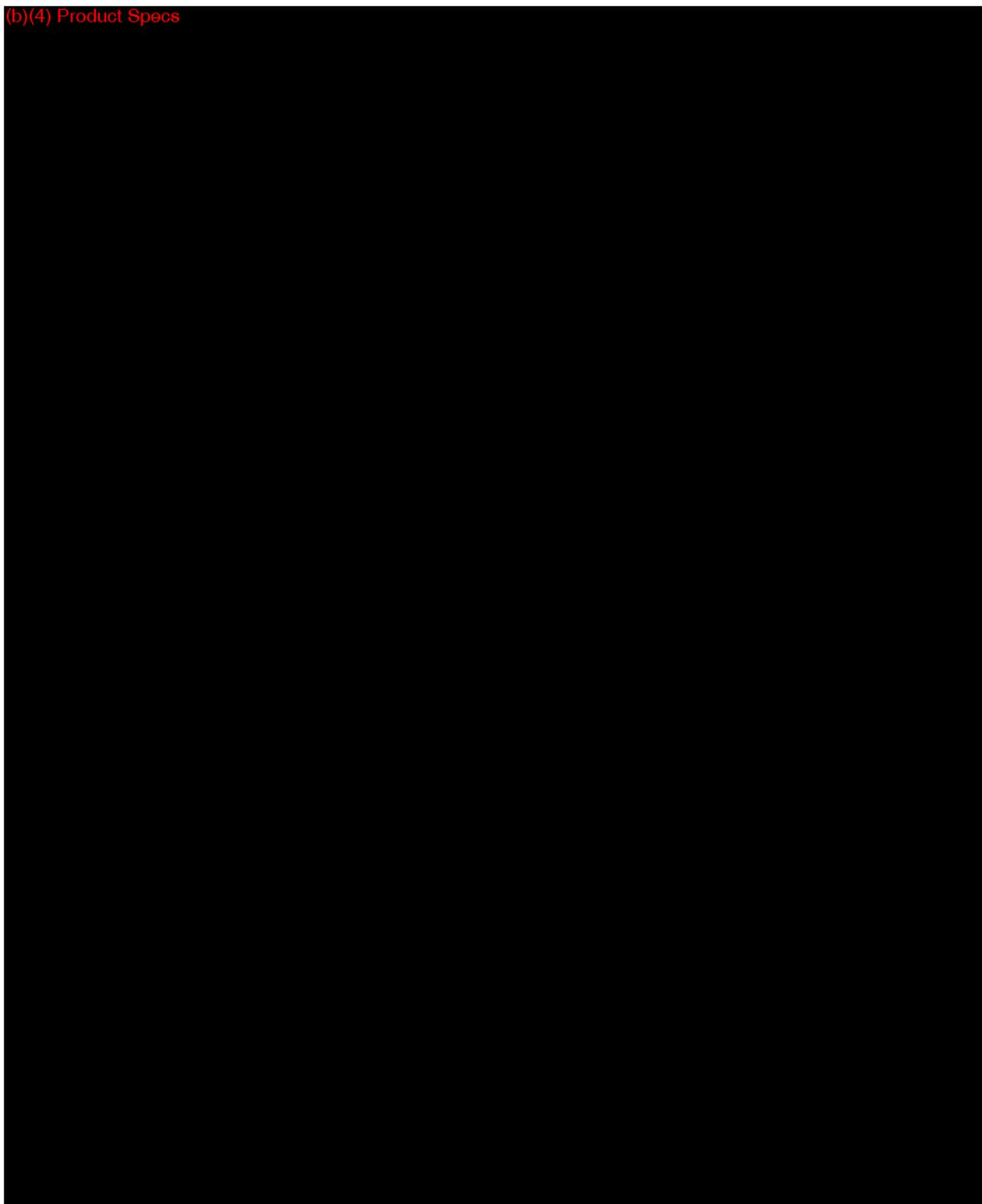
RE: K120562 – PerforMax Pediatric EE Total Face Mask

Dear Mr. Lee:

(b)(4) Product Specs



(b)(4) Product Specs



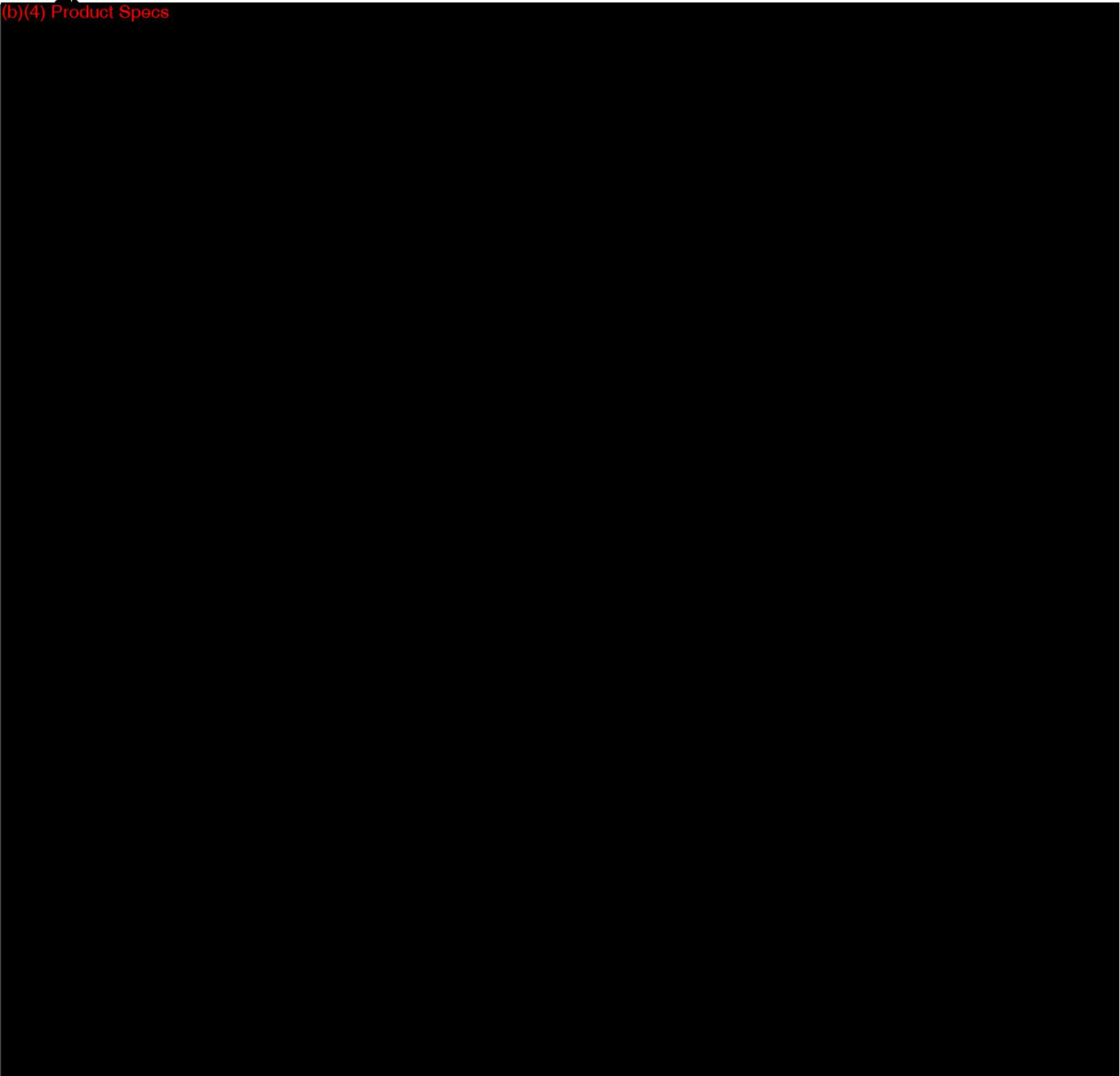


(b)(4) Product Specs



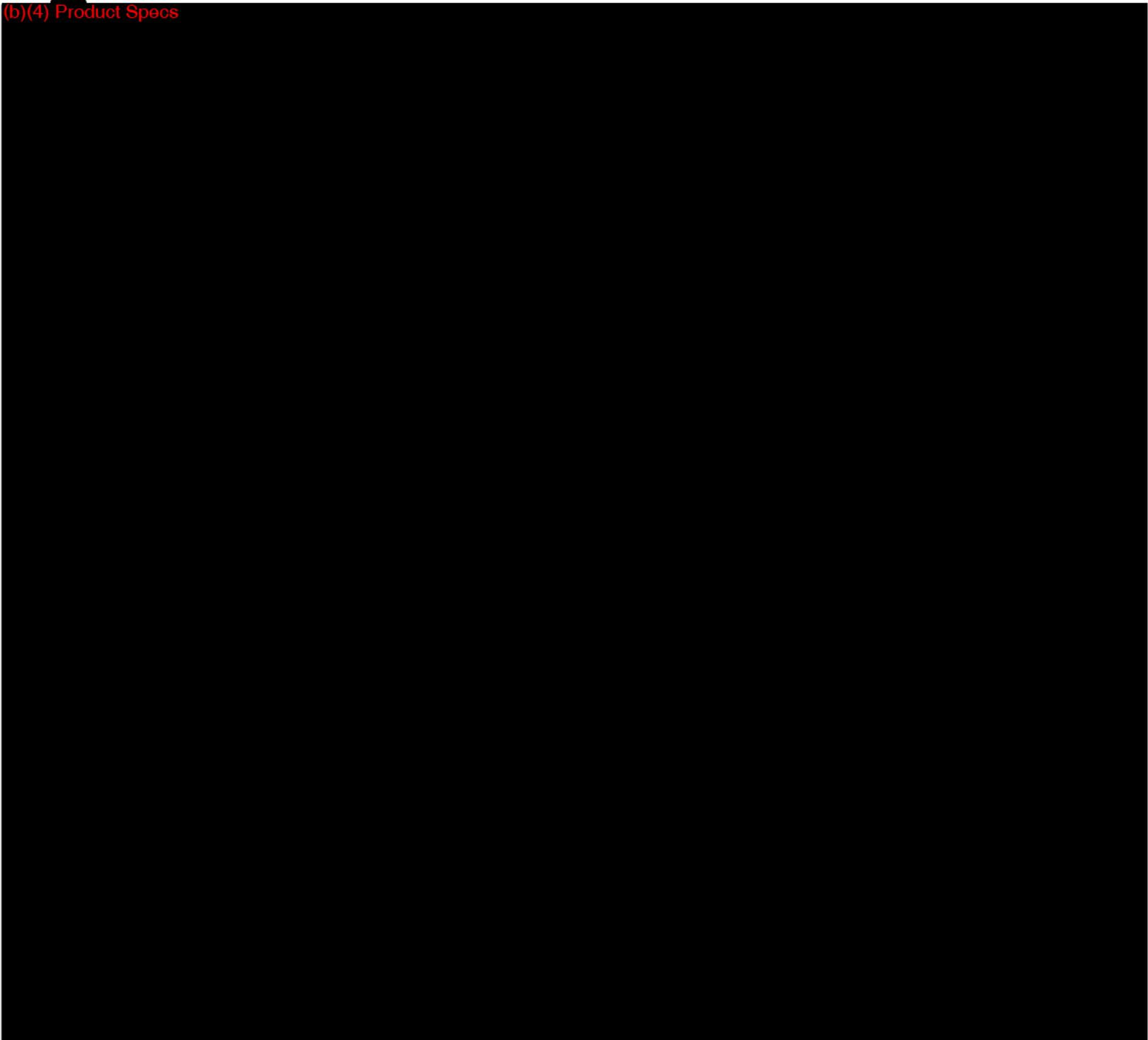


(b)(4) Product Specs



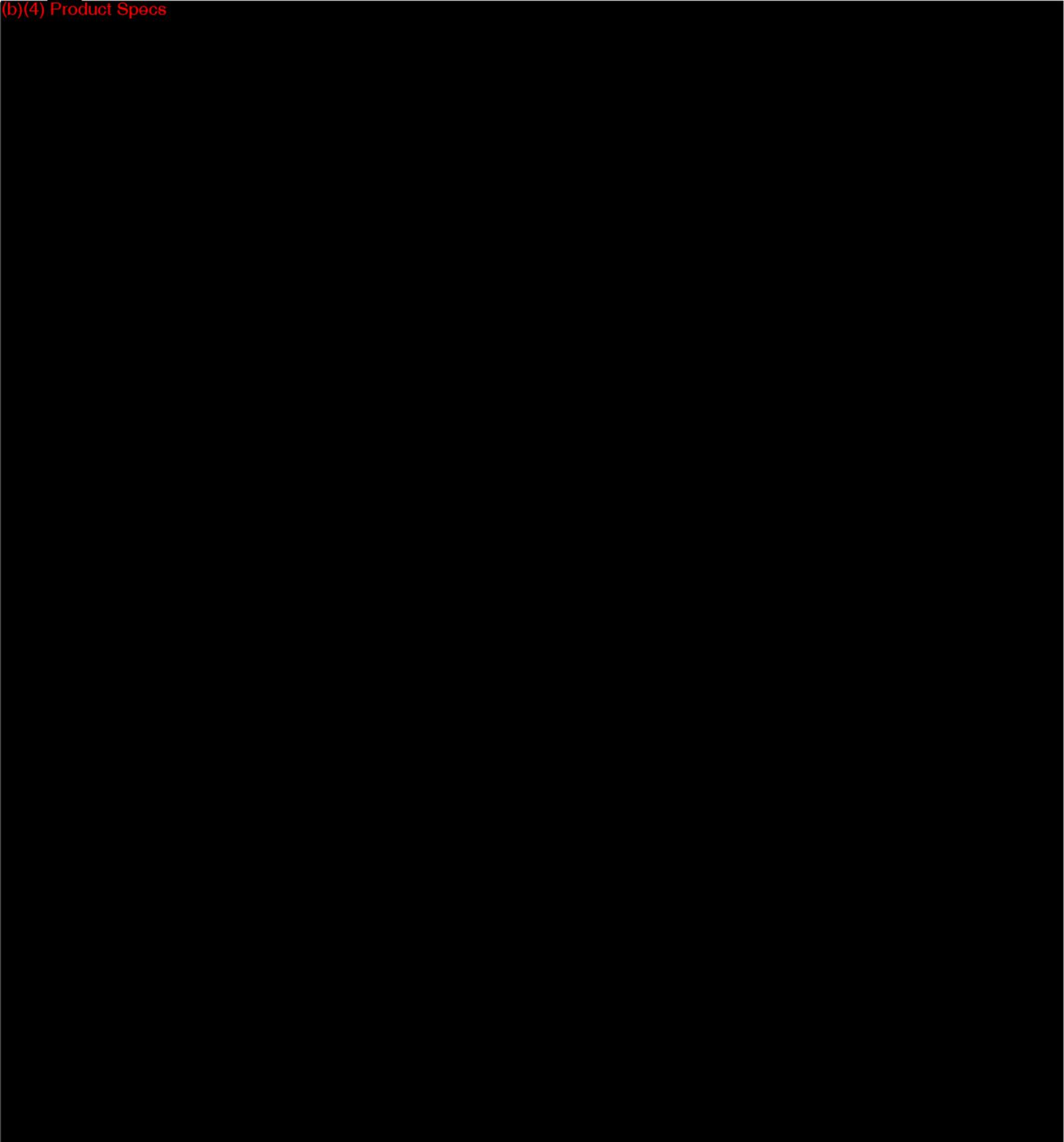


(b)(4) Product Specs





(b)(4) Product Specs



(b) (4)

This comparison showed that the proposed PerforMax Pediatric mask has an intended use that is considered to be as safe and effective as the predicate masks. Further, the PerforMax Pediatric mask has design features that are the same as or similar to one or both of the predicate masks. Guidance from the ISO 17510-2 standard was used as an input into the development of the PerforMax Pediatric mask and the predicate mask designs. The test data provided in Tables 1-4 demonstrates that the performance of the proposed PerforMax Pediatric mask is substantially equivalent to the predicate devices.

It is concluded that the PerforMax Youth mask and Small Child Profile Lite mask are suitable predicates for the proposed PerforMax Pediatric mask based on this comparison of the key mask characteristics. The intended use, design and performance of the PerforMax Pediatric mask are substantially equivalent to the predicate masks. The PerforMax Pediatric mask does not raise new issues of safety or effectiveness.

If you should require any additional information, please contact me at 724-387-4146 (office), 412-209-8665 (cell) or by email at Michelle.Brinker@Philips.com.

Thank you again for your review.

Sincerely,

(b) (6)

Michelle Brinker
Regulatory Affairs Manager, Patient Interface



DEPARTMENT OF HEALTH & HUMAN SERVICES

K120562 / S2 VI

Public Health Service

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

June 22, 2012

RESPIRONICS, INC.
SLEEP AND HOME RESPIRATORY GROUP
365 PLUM INDUSTRIAL COURT
PITTSBURGH, PENNSYLVANIA 15239
ATTN: MICHELLE BRINKER

510k Number: K120562

Product: PERFORMAX PEDIATRIC EE TOTAL F

On Hold As of 6/21/2012

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/MedicalDeviceProvisionsofFDAModer nizationAct/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.

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

K120562/S2

* * * COMMUNICATION RESULT REPORT (JUN. 22. 2012 2:03PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : JUN. 22. 2012 2:00PM
FAX MODE OPTION

ADDRESS

RESULT

PAGE

6830 MEMORY TX

917243873999

OK

2/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWER

E-2) BUSY
E-4) NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO65-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 22, 2012

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COVER SHEET MEMORANDUM

From: Reviewer Name

James Lee

Subject: 510(k) Number

K120562/32

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 (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

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)?			
For United States-based clinical studies only : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, 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.)

Transitional Adolescent B (18 - ≤ 21 ; No special considerations compared to adults $\Rightarrow 21$ 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 868.5905	Class II	B+D

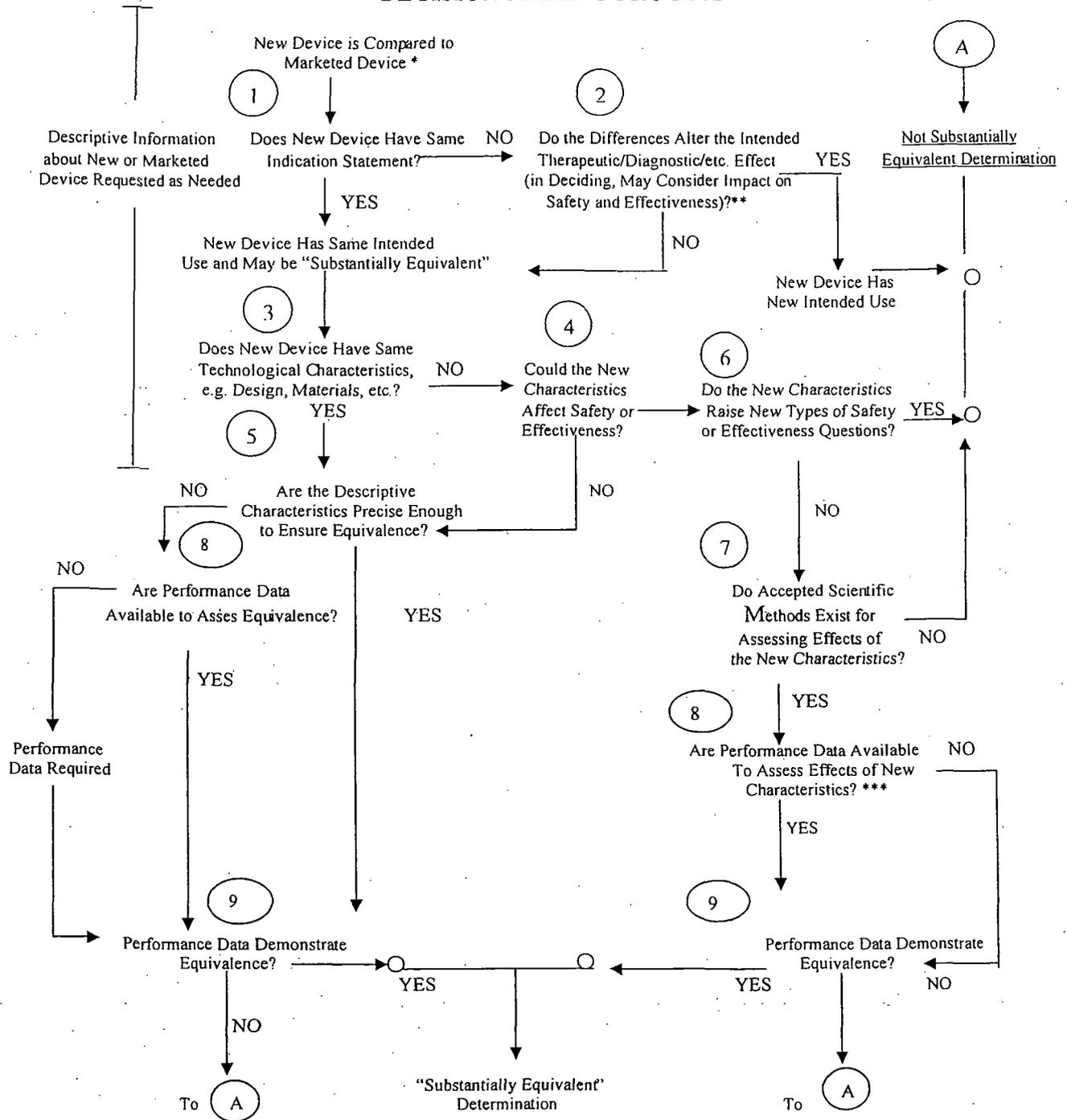
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: J. Schuler (Branch Chief) ARDB (Branch Code) 6/24/12 (Date)

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

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.



Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K120562/S002

Date: June 21, 2012
To: The Record
From: James Lee PhD
510(k) Holder: RESPIRONICS INC
Device Name: PerforMax Pediatric EE Total Face Mask
Contact: Michelle Brinker
Phone: (724) 387-4146
Fax: (724) 387-3999
Email: michelle.brinker@philips.com

Office:
Division: DAGID/ARDB

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the Respiroics PerforMax Pediatric EE Total Face Mask into interstate commerce. The PerforMax Pediatric EE Total Face Mask is a modification in design to the Respiroics PerforMax Youth EE Total Face Mask (previously cleared under K092043) and Respiroics Small Child Profile Lite Nasal Mask (previously cleared under K093416). The modifications consist of the following:

- 1. Updated environment to restrict to hospital/institutional use only
2. Reduced size of the faceplate and cushion
3. Modified elbow
4. Modified the mask operating pressure range, replaced unintentional leak specification with total mask leak specification, and added inspiratory and expiratory resistance specification
5. Material changes for the elbow hub, elbow body, and headgear

The modified device is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The PerforMax Pediatric EE Total Face Mask is for patients 1 year or older (> 7 kg). The mask is for multi-patient use in the hospital / institutional environment only.

II. Administrative Requirements

Table with 4 columns: Requirement, Status, Yes, No, N/A. Rows include: Indications for Use page, Truthful and Accuracy Statement, 510(k) Summary or 510(k) Statement, Standards Form.

510(k) Summary

The sponsor has provided its 510(k) Summary in Section 5.

Required Elements for 510(k) Summary (21 CFR 807.92)		
	Clearly labeled "510(k) Summary"	yes
	Submitter's name, address, phone #, a contact person	yes
	Date the summary was prepared	yes
	The name of the device/trade name/common name/classification name	yes
	An identification of the legally marketed predicate	yes
	Description of the subject device	yes
	Statement of intended use	yes
Technological characters	if same, a summary of comparison of technological characters	yes
	If different, a summary of how do they compare to the predicate	
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	yes
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> - Description upon whom the device was tested, - Data obtained from the tests and especially: <ul style="list-style-type: none"> ▪ Adverse events and complications ▪ Other information for SE determination 	
	Conclusion that data demonstrate SE	
Required Elements for 510(k) Statement (21 CFR 807.93)		N/A
	Signed verbatim statement	

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?			

The PerforMax Pediatric EE Total Face Mask expands upon the existing Respirationics PerforMax product line, which currently includes a size cleared for patients 7 years and older (> 18.2 kg).

The PerforMax Pediatric EE Total Face Mask consists of a (b) (4) faceplate, a silicone cushion that seals along the perimeter of the face, an elbow with an integral entrainment valve, and an

elbow hub that retains the elbow. A pressure-pick off port is located on the elbow body. The mask is secured to the head with a bonnet style headgear.

The Performax elbow hub allows the medical professional to use the mask with either an Entrainment Elbow (EE) Leak 2 or an Entrainment Elbow (EE) Leak 1. The EE Elbow is a simple press fit assembly into the hub of the mask.

(b) (4)

(b) (4)

The EE Leak 2 elbow has a 6" fixed 15 mm to 22 mm flexible extension tube attached. There is a 22 mm swivel connector at the end of the tubing to attach to standard 22 mm tubing used with CPAP and bi-level systems. The EE Leak 1 elbow connects directly to standard 22 mm tubing used with CPAP and bi-level systems (see Figure 3). The EE Leak 1 elbow does not include an extension tube or swivel. The Performax Pediatric EE Total Face Mask is available in two sizes, XS and XXS.

IV. Indications for Use

Indications for Use as provided in Section 4 of the original submission:

Performax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bilevel system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Prescription Use has been indicated.

Predicate Indications for Use:

Performax Youth EE Total Face Mask (K092043) –

The Respirationics BiPAP Synchrony 2 is intended to provide non-invasive ventilation for pediatric patients 7 years or older (> 40 lbs) or adult patients (> 66 lbs) with respiratory insufficiency or obstructive sleep apnea, in the hospital or home.

Small Child Profile Lite Nasal Mask (K093416) –

The Respirationics Trilogy200 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy200 is intended for pediatric through adult patients weighing at least 5 kg (11 lbs.).

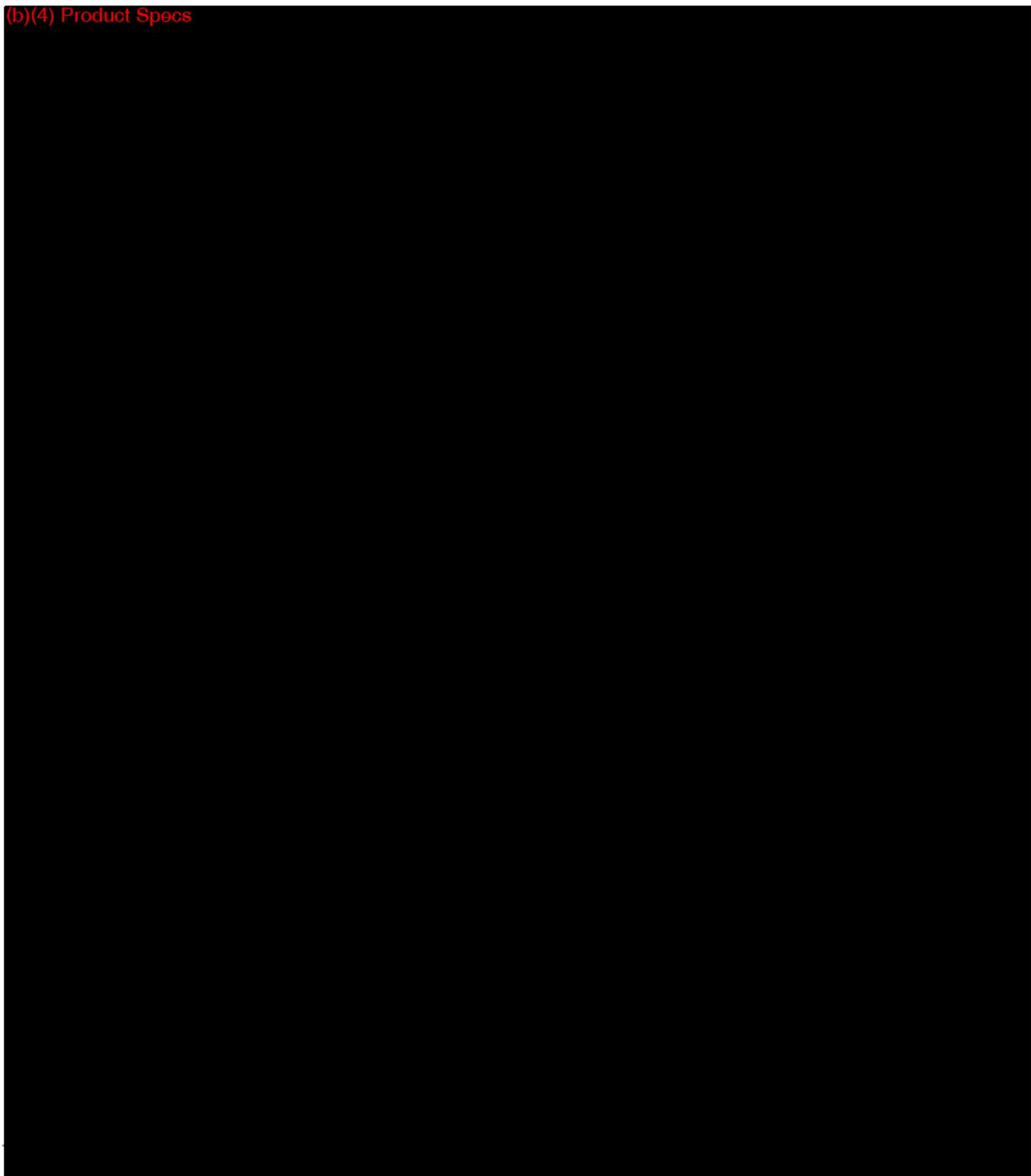
The device is intended to be used in home, institution/hospital, and portable applications such as wheelchairs and gurneys, and may be used for both invasive and non-invasive ventilation

(b) (4)

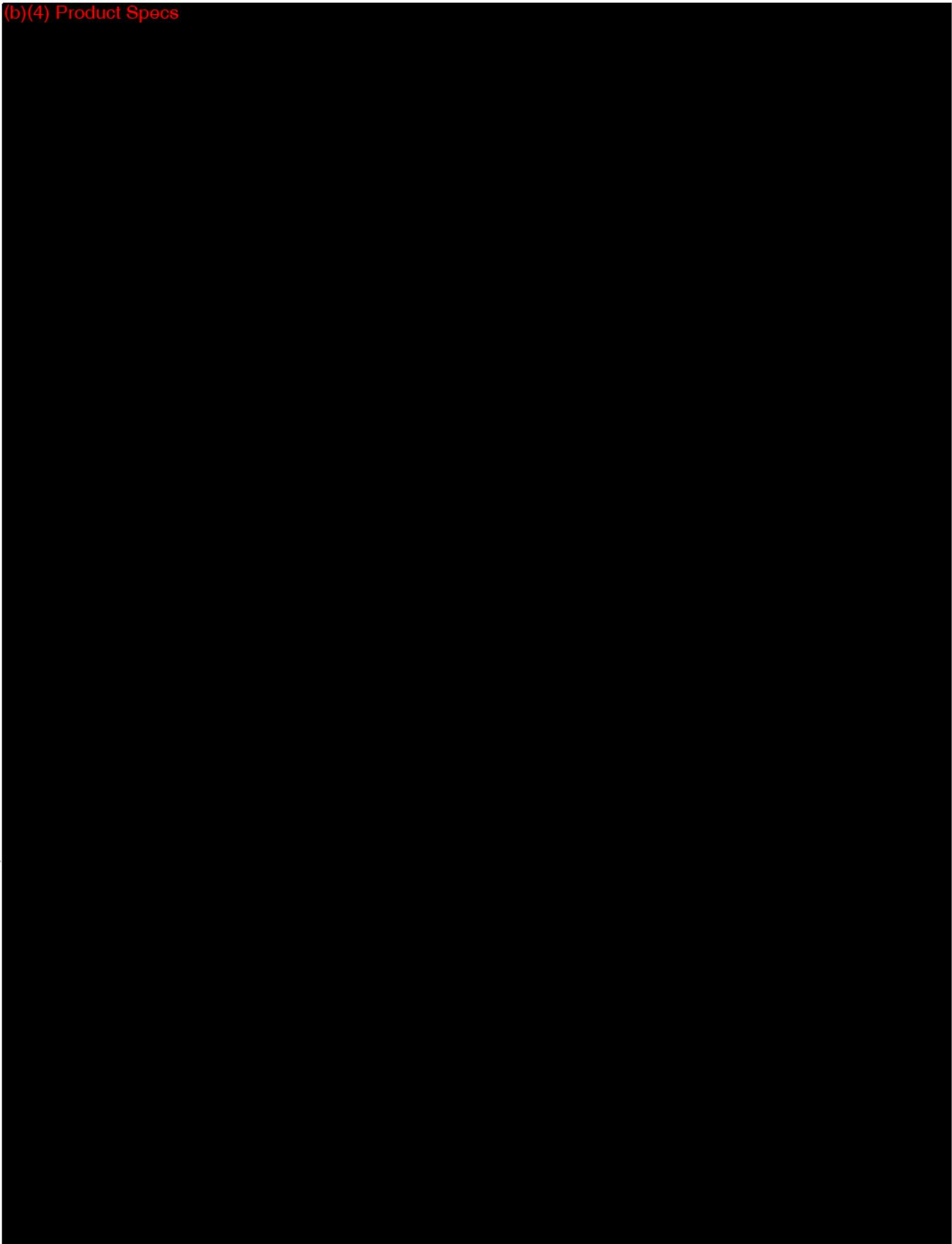
V. Predicate Device Comparison

(b) (4)

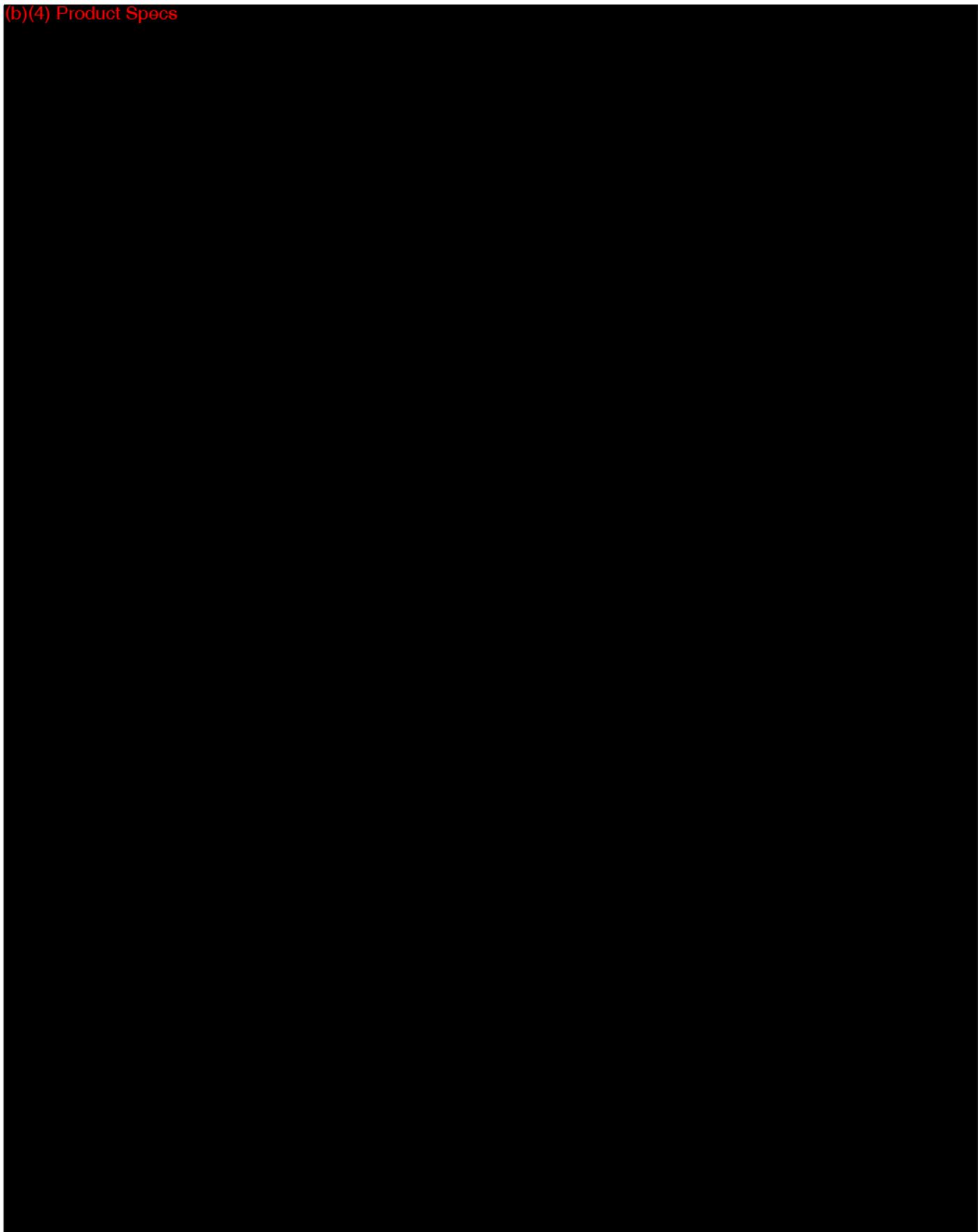
(b)(4) Product Specs



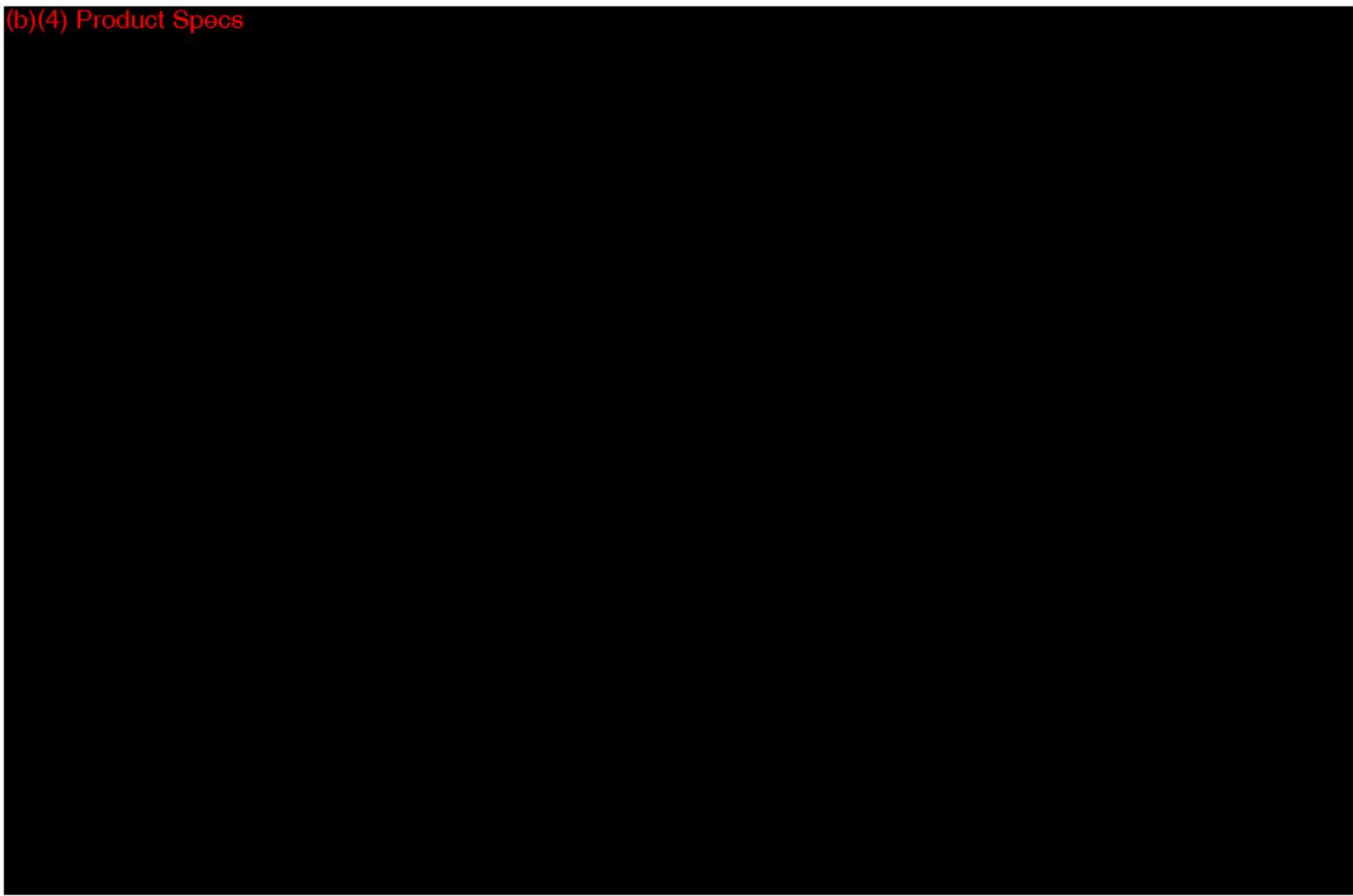
(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs



(b) (4)



VI. Labeling

Draft labeling is provided in TAB 13 of the original submission. This section includes the instructions for use, warning and caution statements, device specifications, and reuse instructions (disinfection). The caution statement for prescription devices as required by 21 CFR 801.109: Caution: "Federal law restricts this device to sale by or on the order of a physician. Appropriate caution and warning statement related to the usage of the device are included.

VII. Sterilization/Shelf Life/Reuse

The efficacy of the disinfection process on the components that are in the air pathway was evaluated for the PerformMax Pediatric EE Total Face Mask, intended for multi-patient use, using the guidance provided in:

- AAMI TIR No. 12-2004, Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for the Device Manufacturer, 23 December 2004
- AAMI TIR No. 30-2003, A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices, 8 October 2003

- ASTM E1837-96 (Re-approved 2002), Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test), Oct. 10, 1996
- ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

VIII. Biocompatibility

A skin contacting and gas pathway materials have been evaluated in accordance with the guidance provided in ISO-10993-1. A declaration of conformity to ISO-10993-1 is provided in Tab 9 of the original submission.

Tab 9A	Declaration of Conformity to ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process <i>Includes summary materials table and exploded assembly diagrams</i> FORM FDA 3654 Standards Data Report for 510(k)s – ISO 10993-1:2009 Summary Report for ISO 10993-1:2009
Tab 15A	Biocompatibility Report (b) (4)
Tab 15B	Biocompatibility Report (b) (4)
Tab 15C	Biocompatibility Report (b) (4)

IX. Software

This device has no software, this section is not applicable.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The device has not electrical or mechanical systems, this section is not applicable.

XI. Performance Testing – Bench

The following is a summary of the bench testing that was performed on the PerforMax Pediatric EE Total Face Mask.

(b) (4)



(b) (4)

[Redacted]

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Environmental Testing

Per the guidance in the FDA Reviewer Guidance for Premarket Notification Submissions, November 1993, testing will be performed to demonstrate safety and effectiveness of the performance characteristics of the device in the intended environment of use and post-storage conditioning. The Intent to Declare Conformance is provided in Tab 9C and test matrix per Appendix A of FDA Reviewer Guidance for Premarket Notification Submissions, November 1993, is provided in Tab 18B.

Risk Assessment

An initial hazards assessment was performed for the PerforMax Pediatric EE Total Face Mask. The assessment analyzed the use situation, the sequence of events, and harm. An initial risk level of the harm was established based on the initial severity and probability classifications (as defined in the risk management plan in Tab 18C).

XII. Performance Testing – Animal

N/A Animal testing not needed to determine substantial equivalence.

XIII. Performance Testing – Clinical

N/A Clinical testing was not submitted to determine substantial equivalence. Submission only has a reference to a clinical study performed in 2000.

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?		x If YES = Stop NSE
3. Same Technological Characteristics?		x If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		x 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?	x	If YES = Stop NSE
7. Accepted Scientific Methods Exist?	x	If NO = Stop NSE
8. Performance Data Available?	x	If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

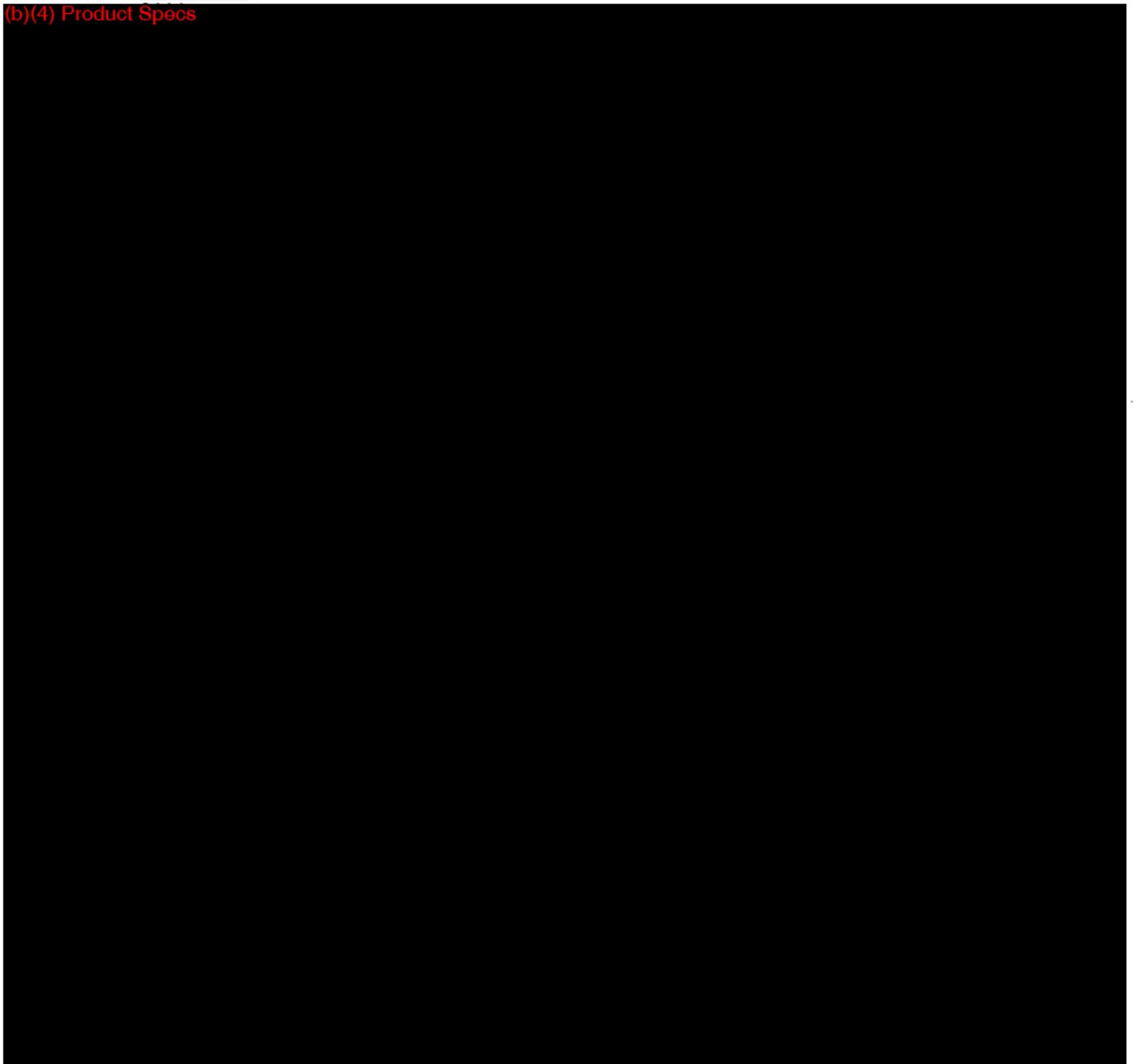
Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. 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:
Additional information regarding the verification and validation activities is needed in order to determine substantial equivalence.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not 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:

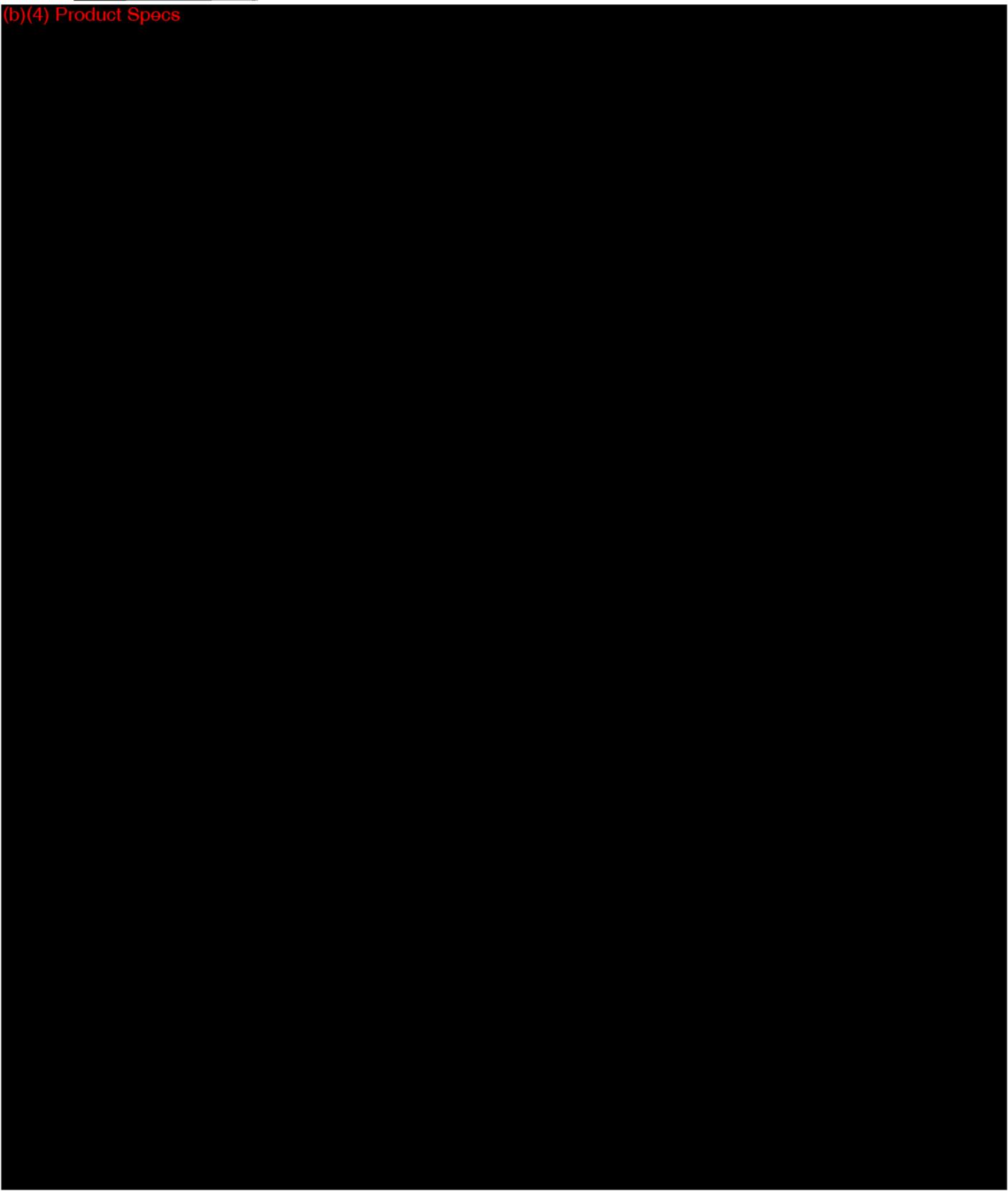
XV. Deficiencies

(b)(4) Product Specs

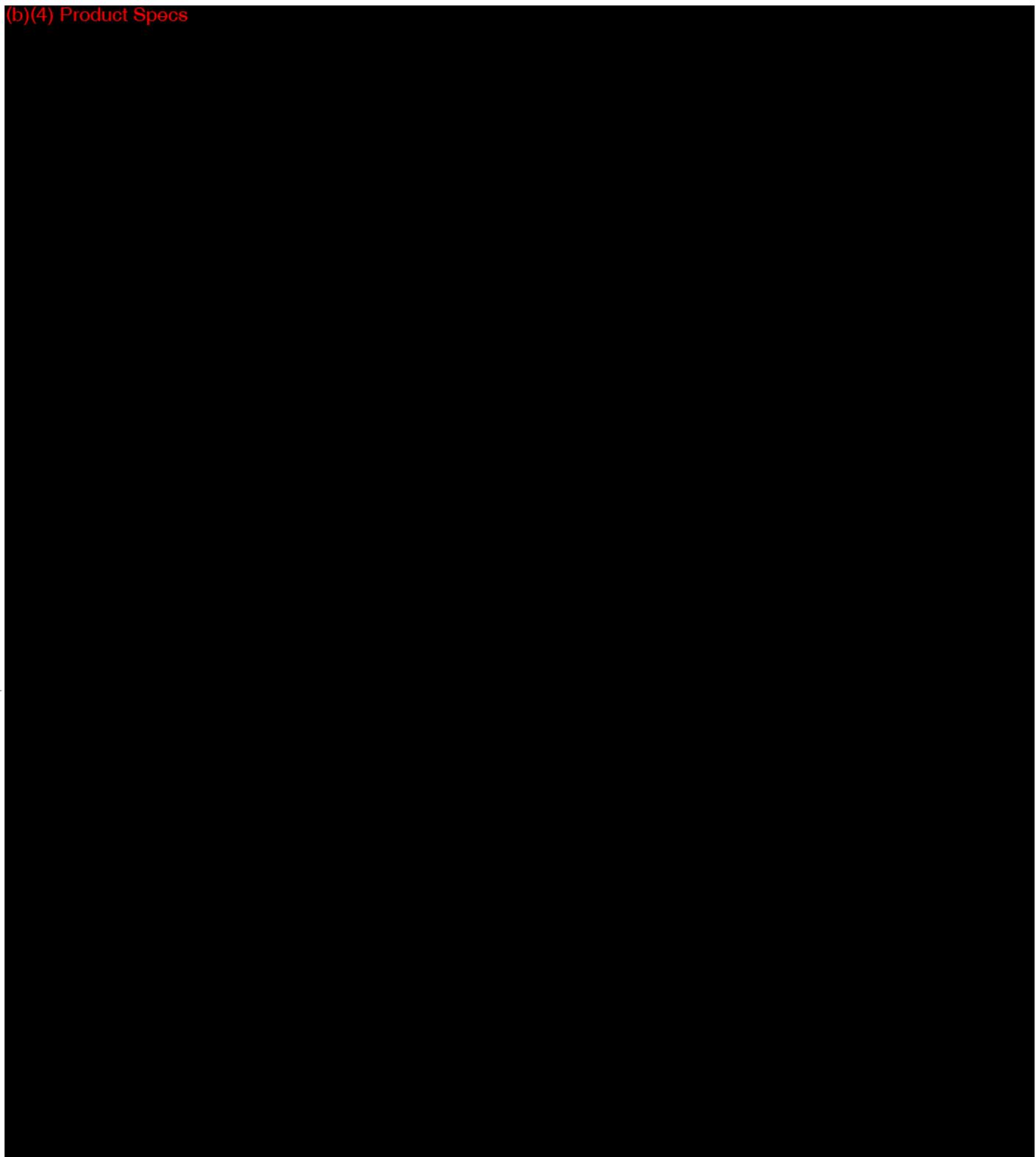


Deficiencies in S001

(b)(4) Product Specs

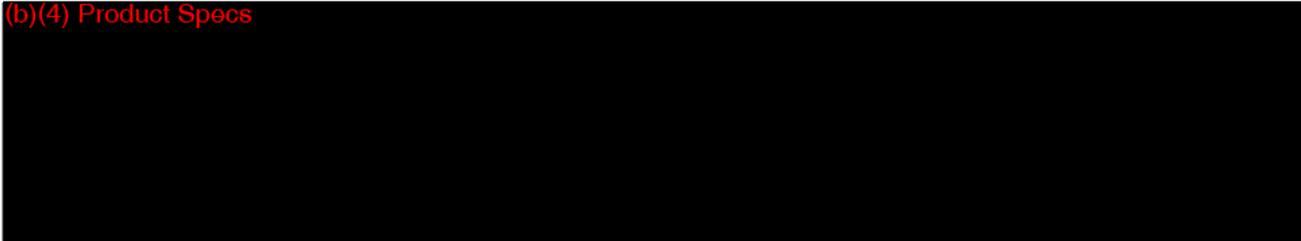


(b)(4) Product Specs



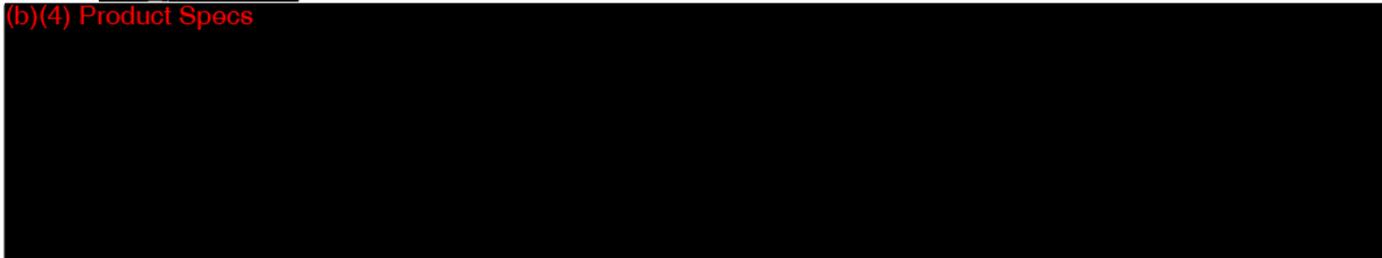
Deficiencies in S002

(b)(4) Product Specs



XVI. Contact History

(b)(4) Product Specs

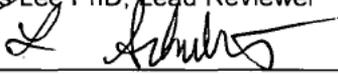


XVII. Recommendation

I recommend that the file be placed on hold pending the receipt of additional information.

Regulation Number: 21 CFR 868.5905
Regulation Name: Nasal Mask
Regulatory Class: Class II
Product Code: BZD



James Lee PhD, Lead Reviewer


Lex Schultheis, MD, PhD, ARDB Branch Chief

6.21.2012

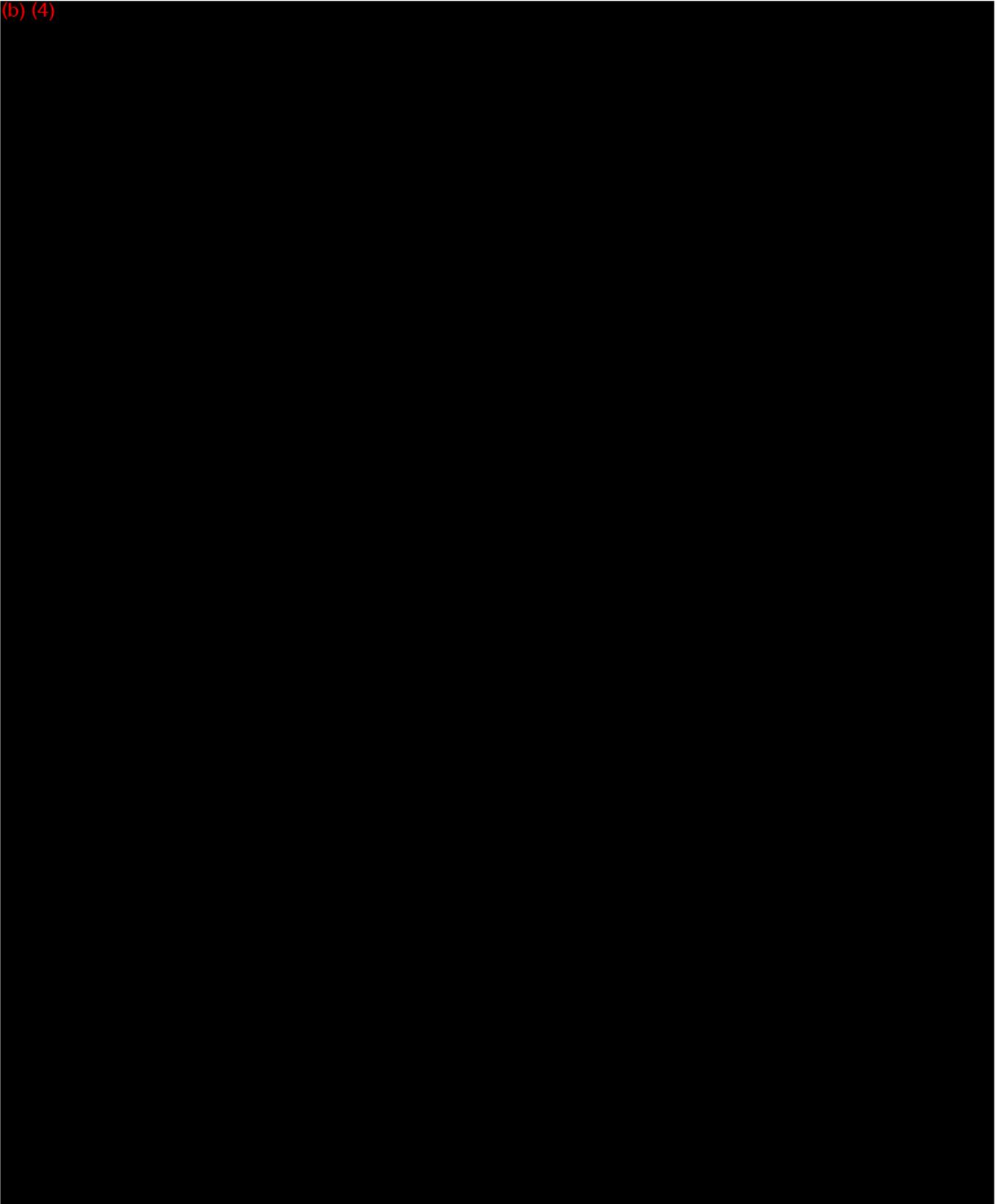
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6/21/12

Date

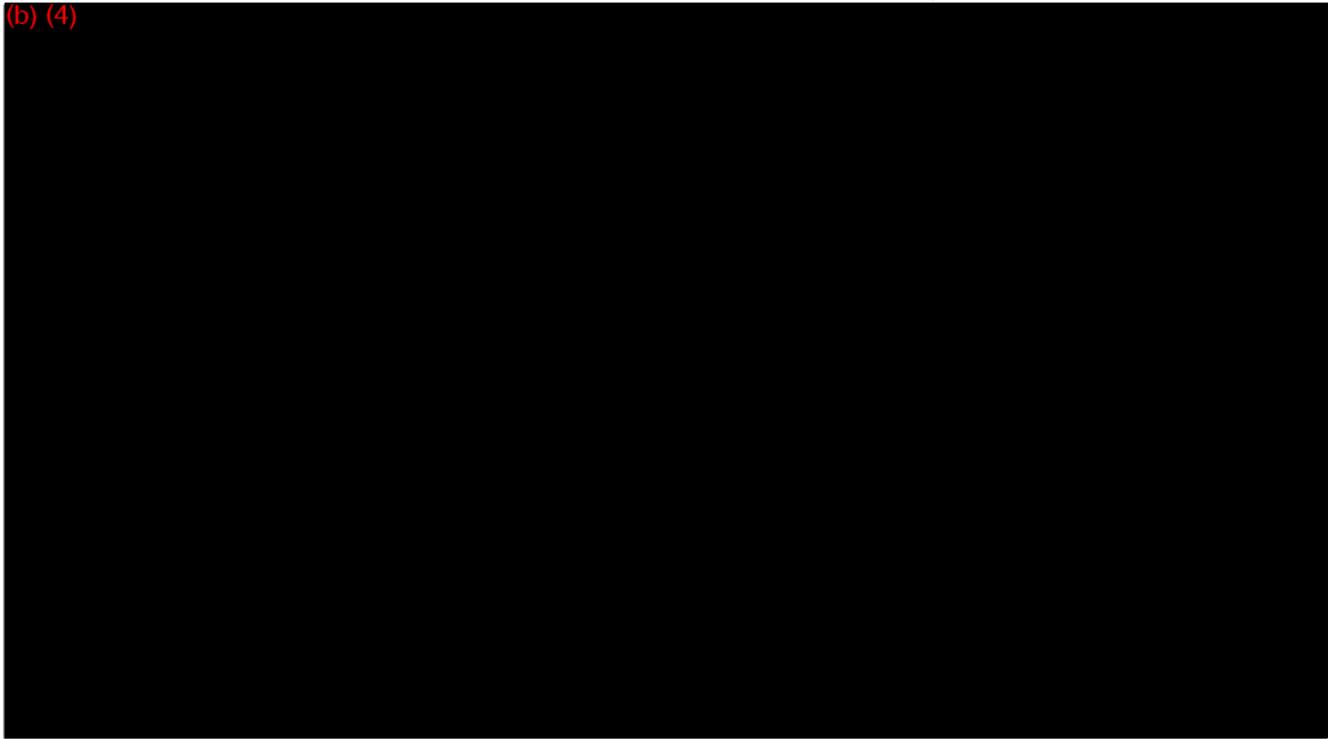
June 21, 2012

Dear Michelle Brinker,

(b) (4)



(b) (4)



Thank You,

James Lee Ph.D., M.S.E.
Interdisciplinary Scientist, Biomedical Engineer
FDA/ODE/CDRH/DAGID/ARDB
10903 New Hampshire Ave.
Silver Spring, MD 20993
james.j.lee@fda.hhs.gov
(301) 796-8463



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

June 18, 2012

RESPIRONICS, INC.
SLEEP AND HOME RESPIRATORY GROUP
365 PLUM INDUSTRIAL COURT
PITTSBURGH, PENNSYLVANIA 15239
ATTN: MICHELLE BRINKER

510k Number: K120562

Product: PERFORMAX PEDIATRIC EE TOTAL F

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Microsoft Outlook
To: 'michelle.brinker@philips.com'
Sent: Monday, June 18, 2012 11:34 AM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'michelle.brinker@philips.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Monday, June 18, 2012 11:34 AM
To: 'michelle.brinker@philips.com'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center WO66-G609
 10903 New Hampshire Avenue
 Silver Springs, MD 20993-5002

June 18, 2012

BRINKER,
 MICHELLE
 RESPIRONICS, INC.
 SLEEP AND HOME RESPIRATORY GROUP
 365 PLUM INDUSTRIAL COURT
 PITTSBURGH, PENNSYLVANIA 15239
 ATTN: MICHELLE BRINKER

510k Number: K120562

Product: PERFORMAX PEDIATRIC EE TOTAL F

The additional information you have submitted has been received.

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

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

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

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

Sincerely,
 510(k) Staff

6/18/2012

K120562/82
June 15, 2012

ATTN: Mr. James Lee, Ph.D., M.S.E.
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

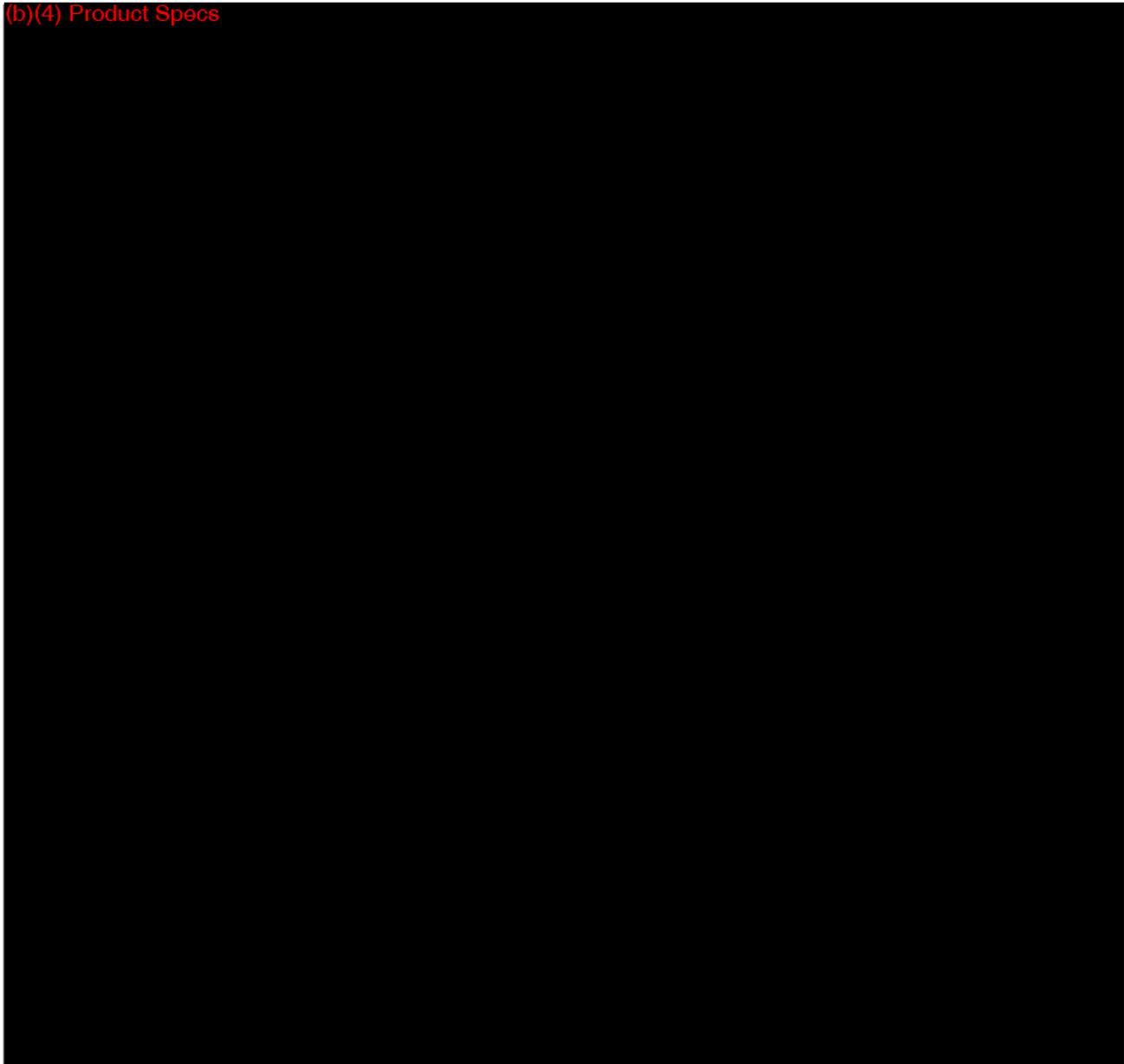
JUN 18 2012

Received K4H

RE: K120562 – PerforMax Pediatric EE Total Face Mask

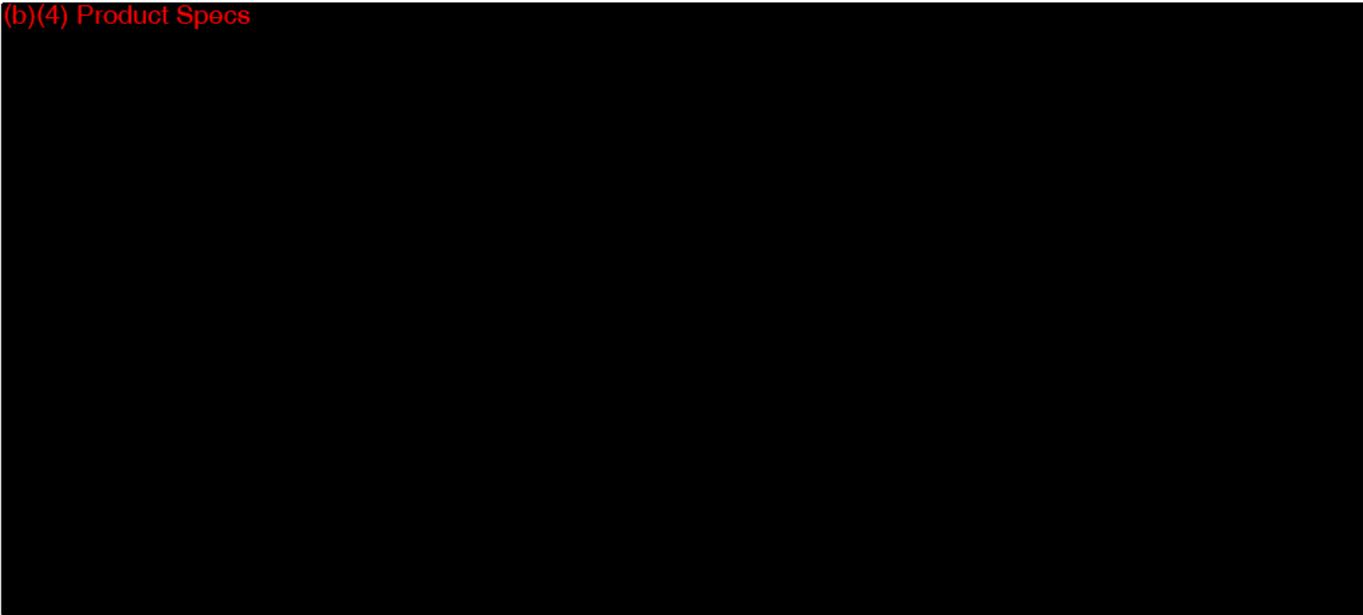
Dear Mr. Lee:

(b)(4) Product Specs

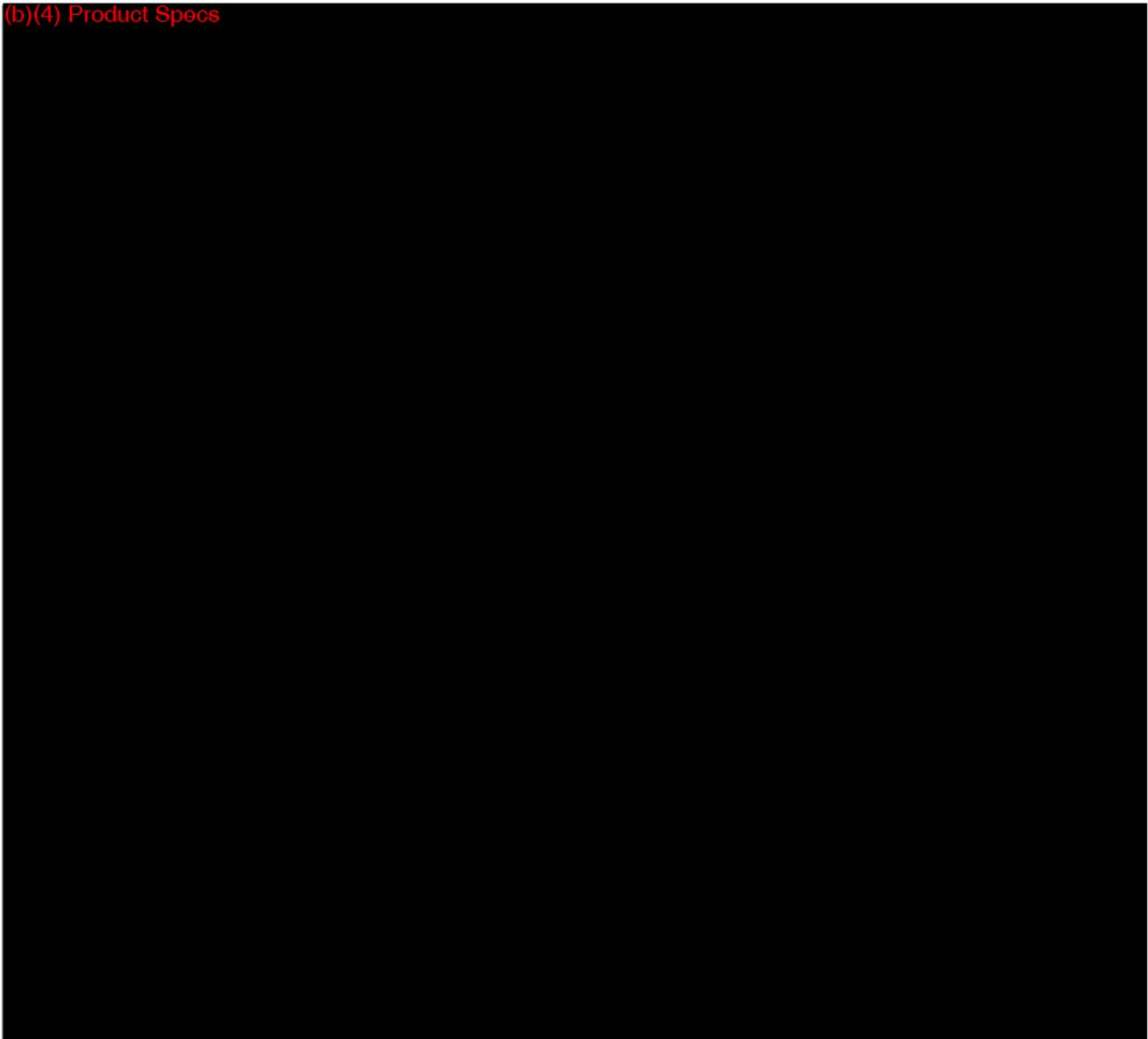




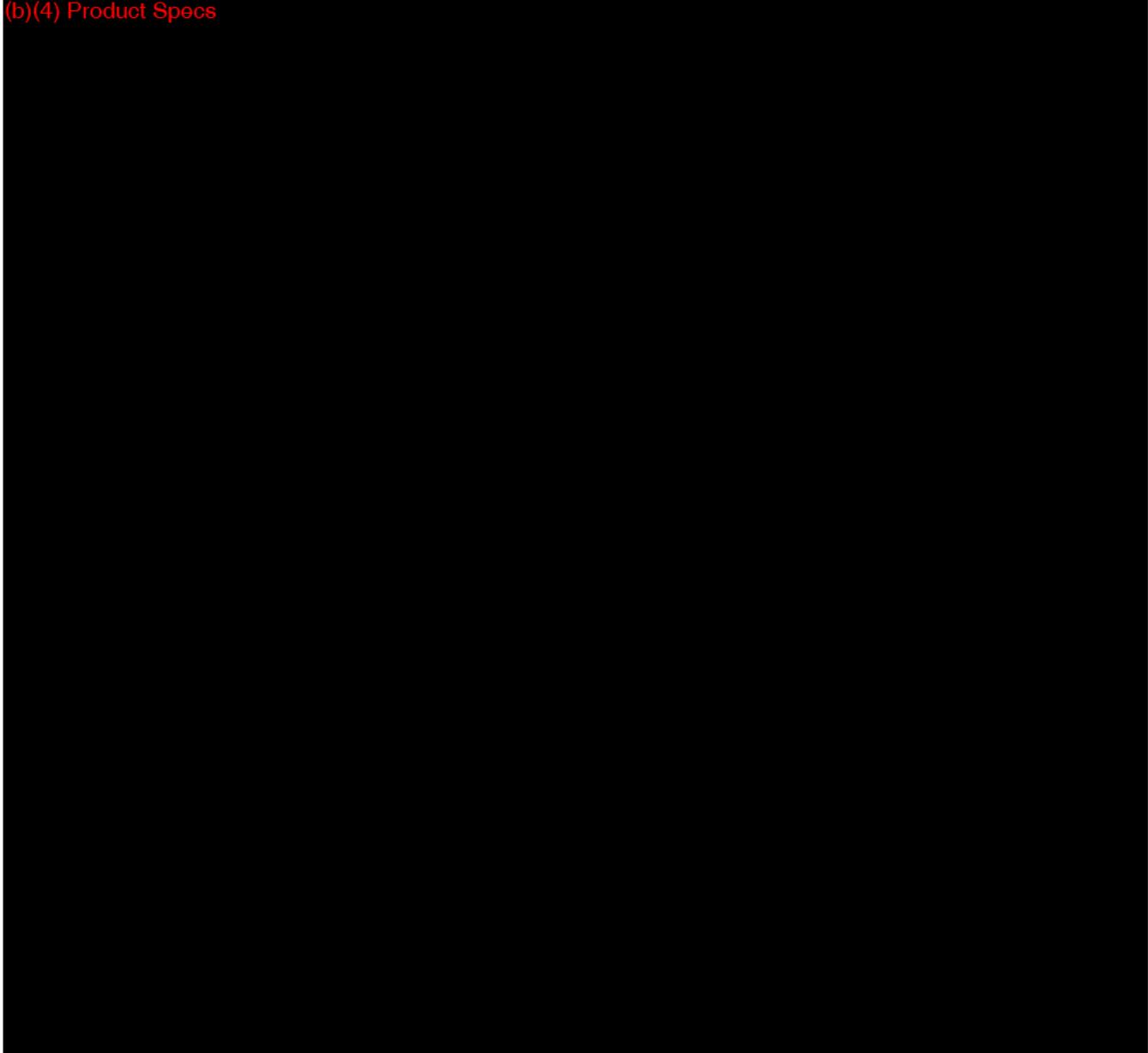
(b)(4) Product Specs



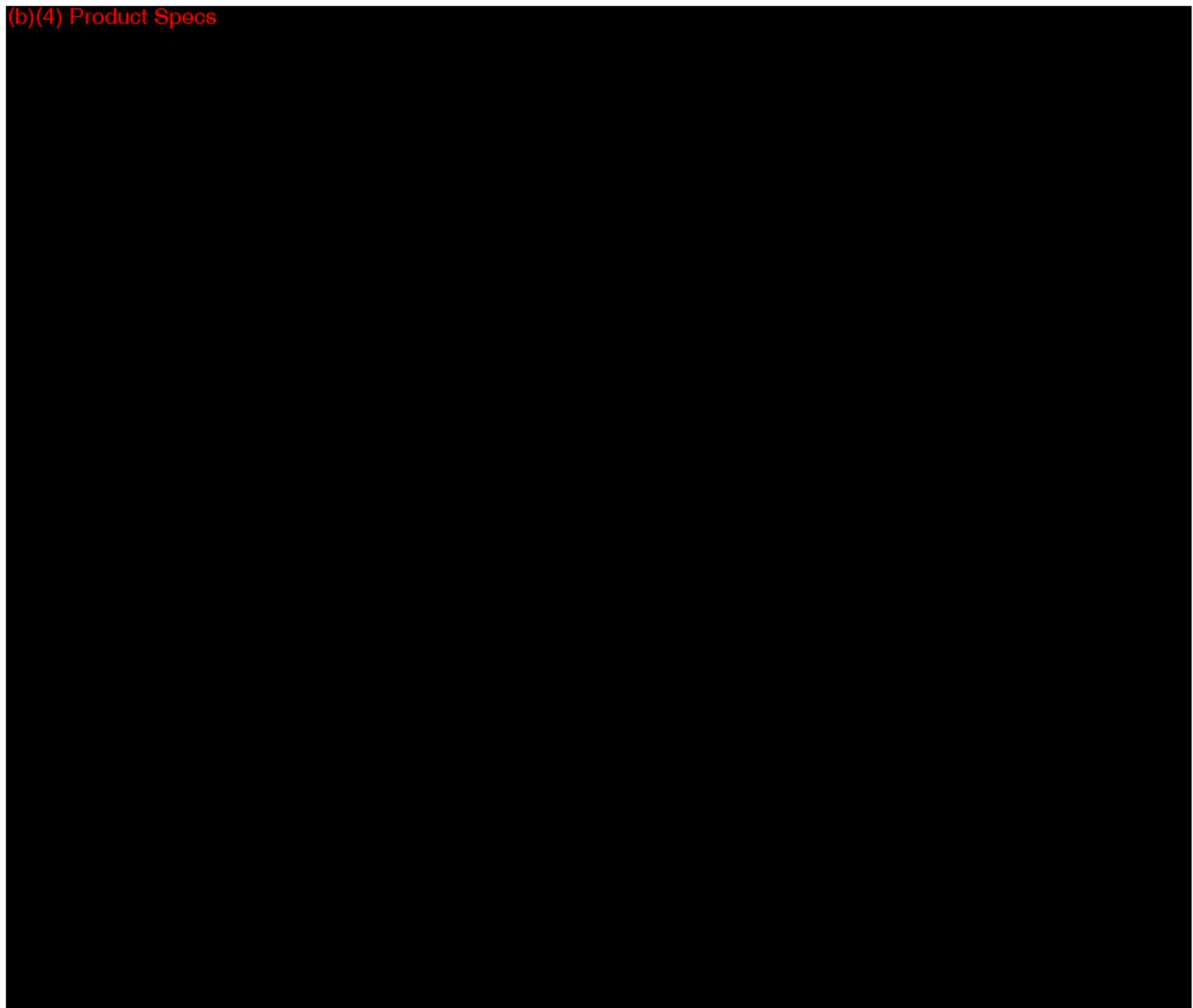
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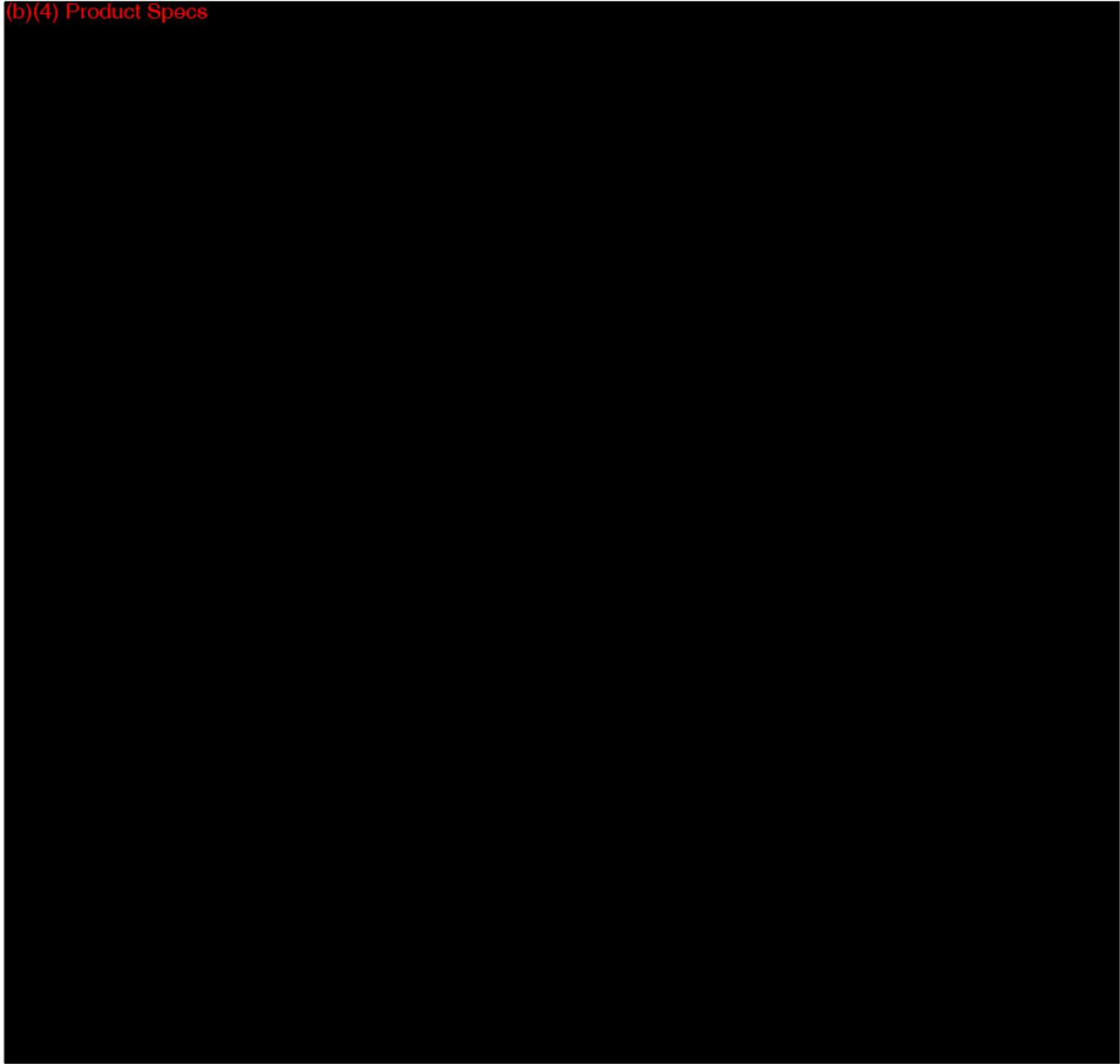
(b)(4) Product Specs



(b)(4) Product Specs

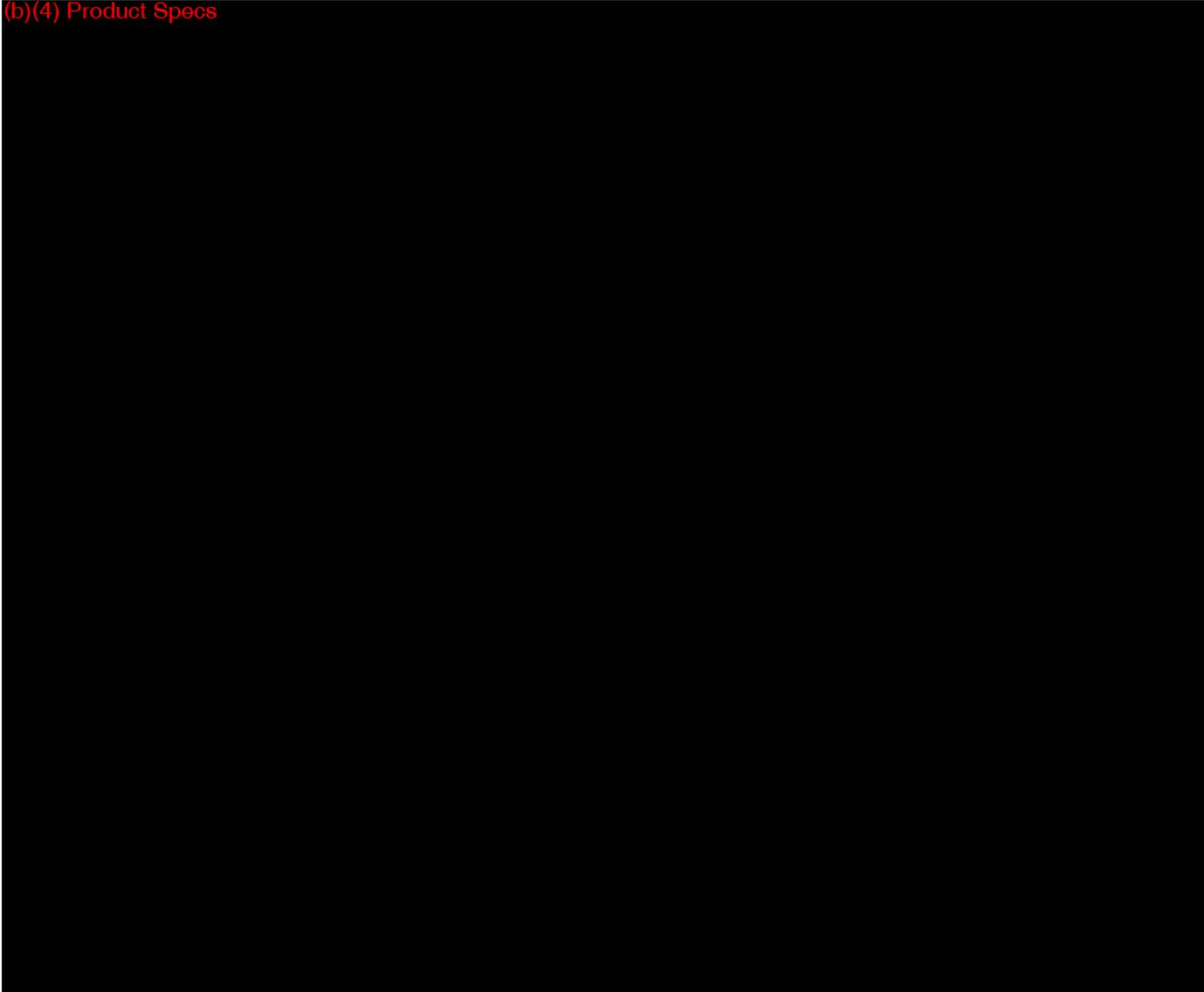


(b)(4) Product Specs

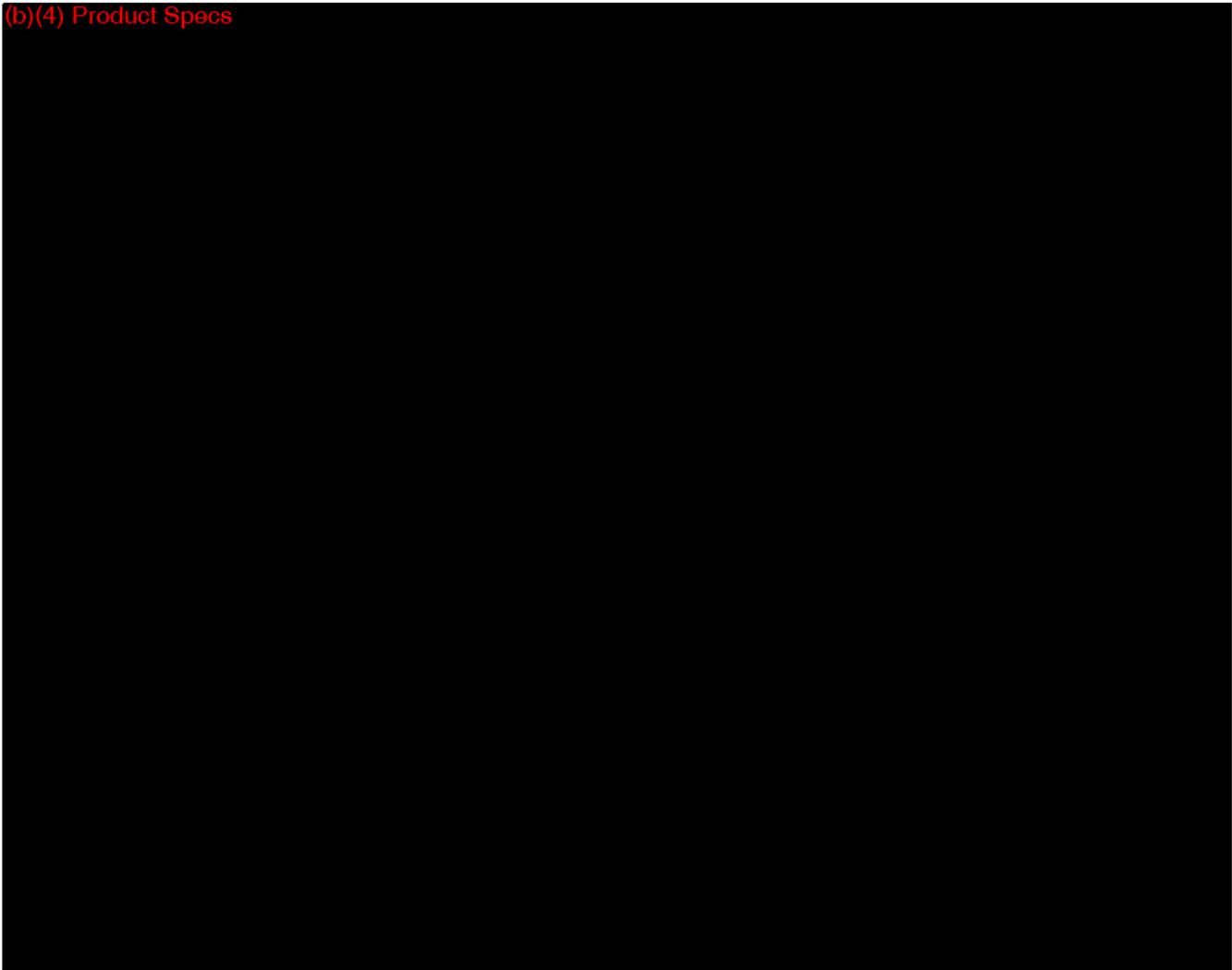




(b)(4) Product Specs

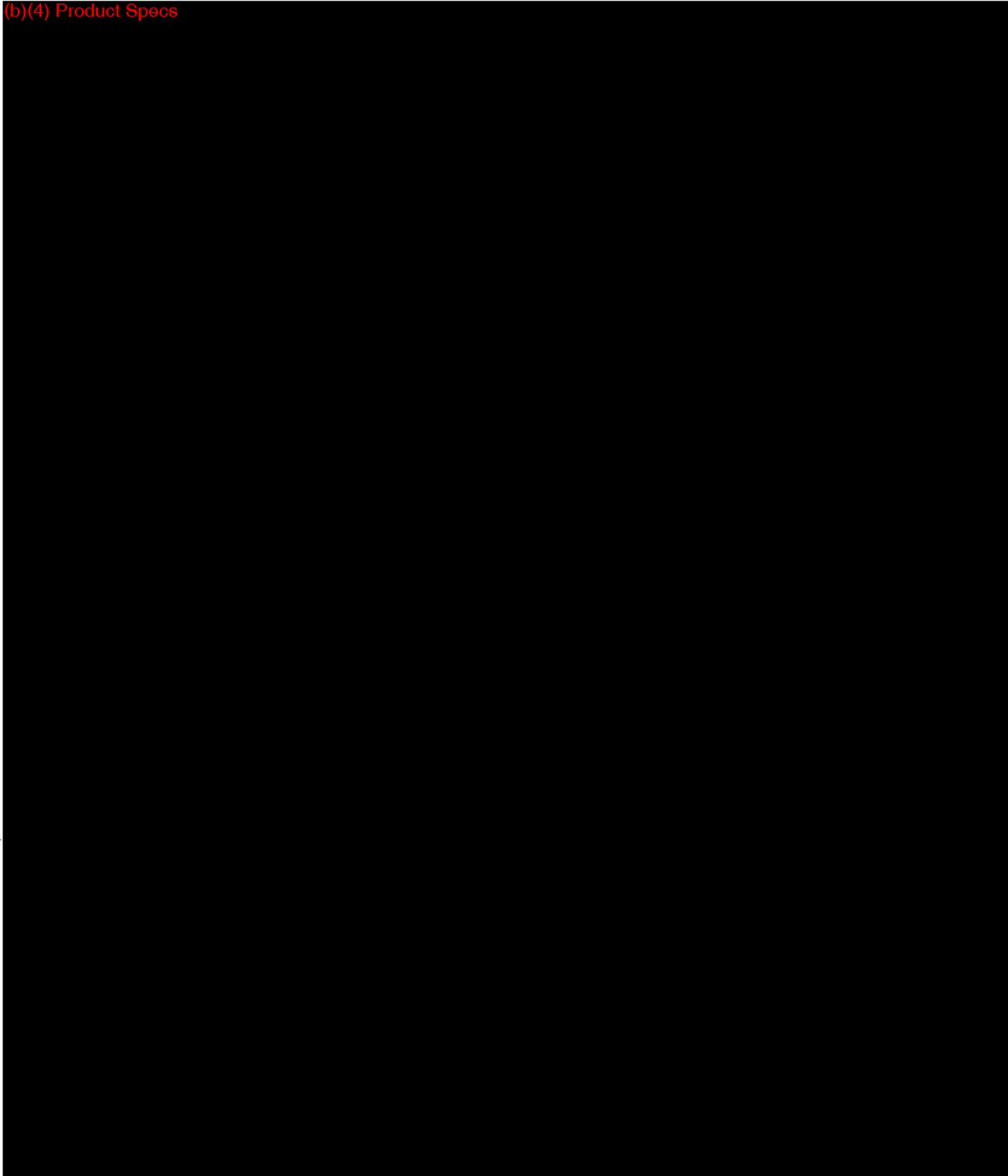


(b)(4) Product Specs

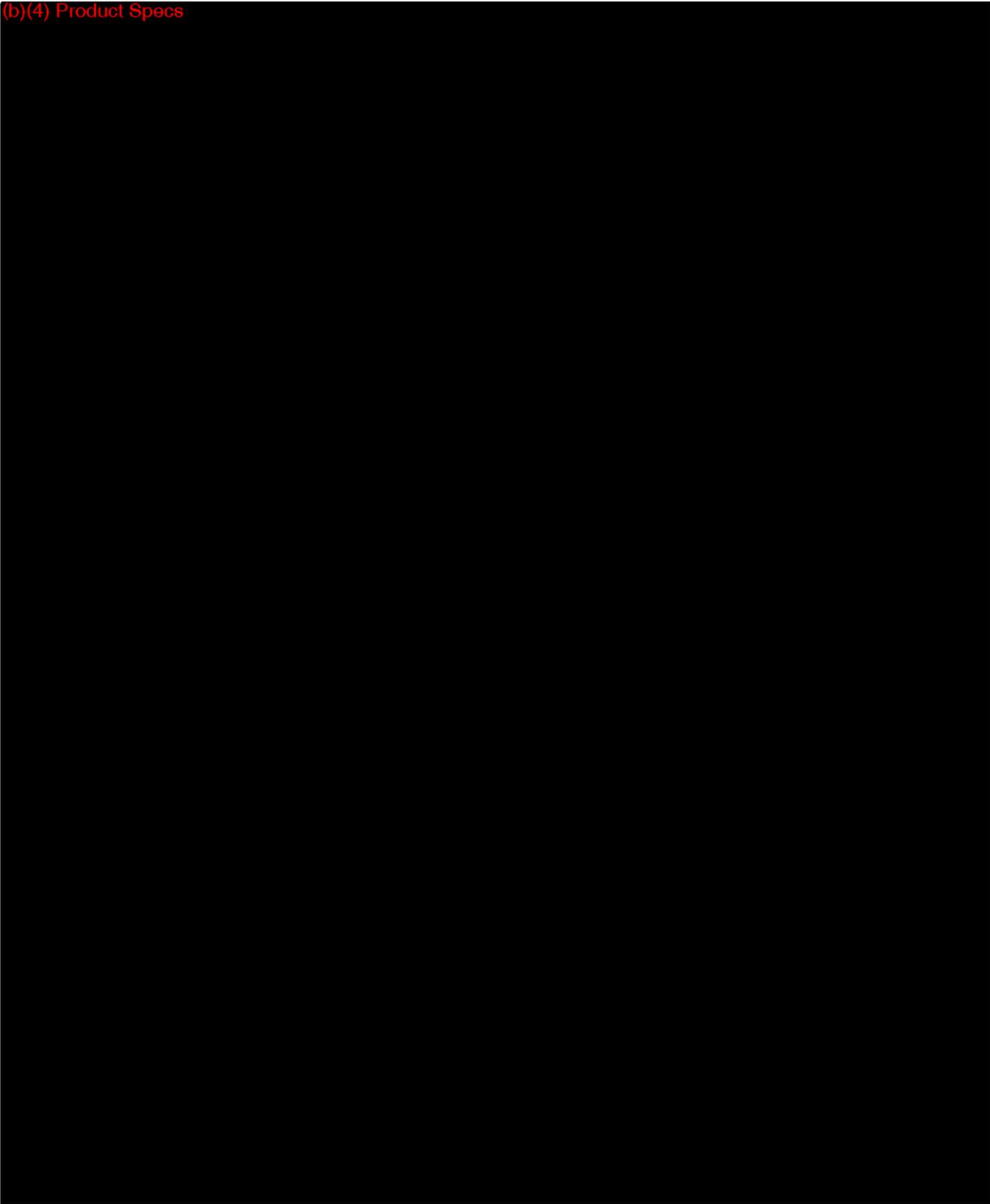




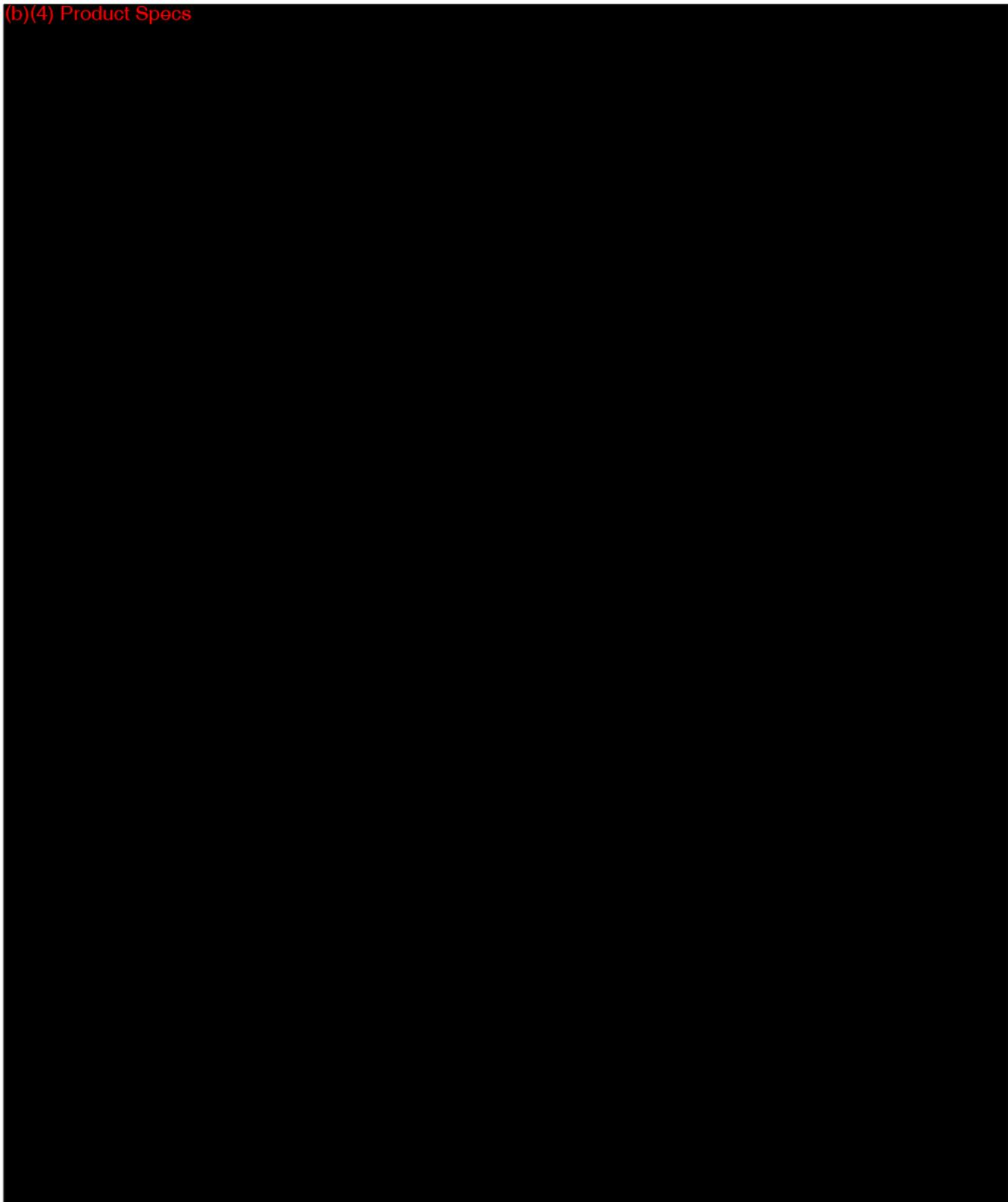
(b)(4) Product Specs



(b)(4) Product Specs

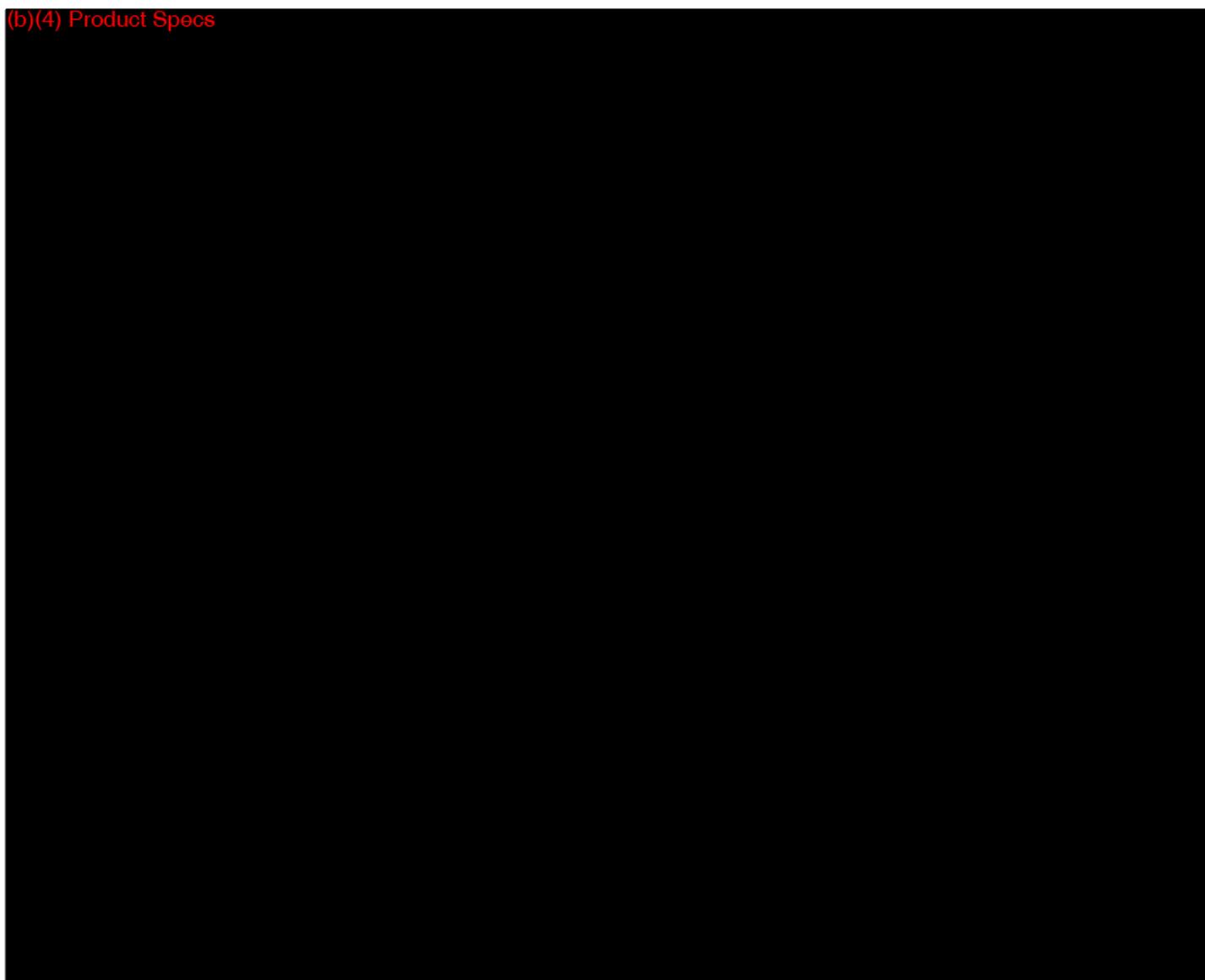


(b)(4) Product Specs



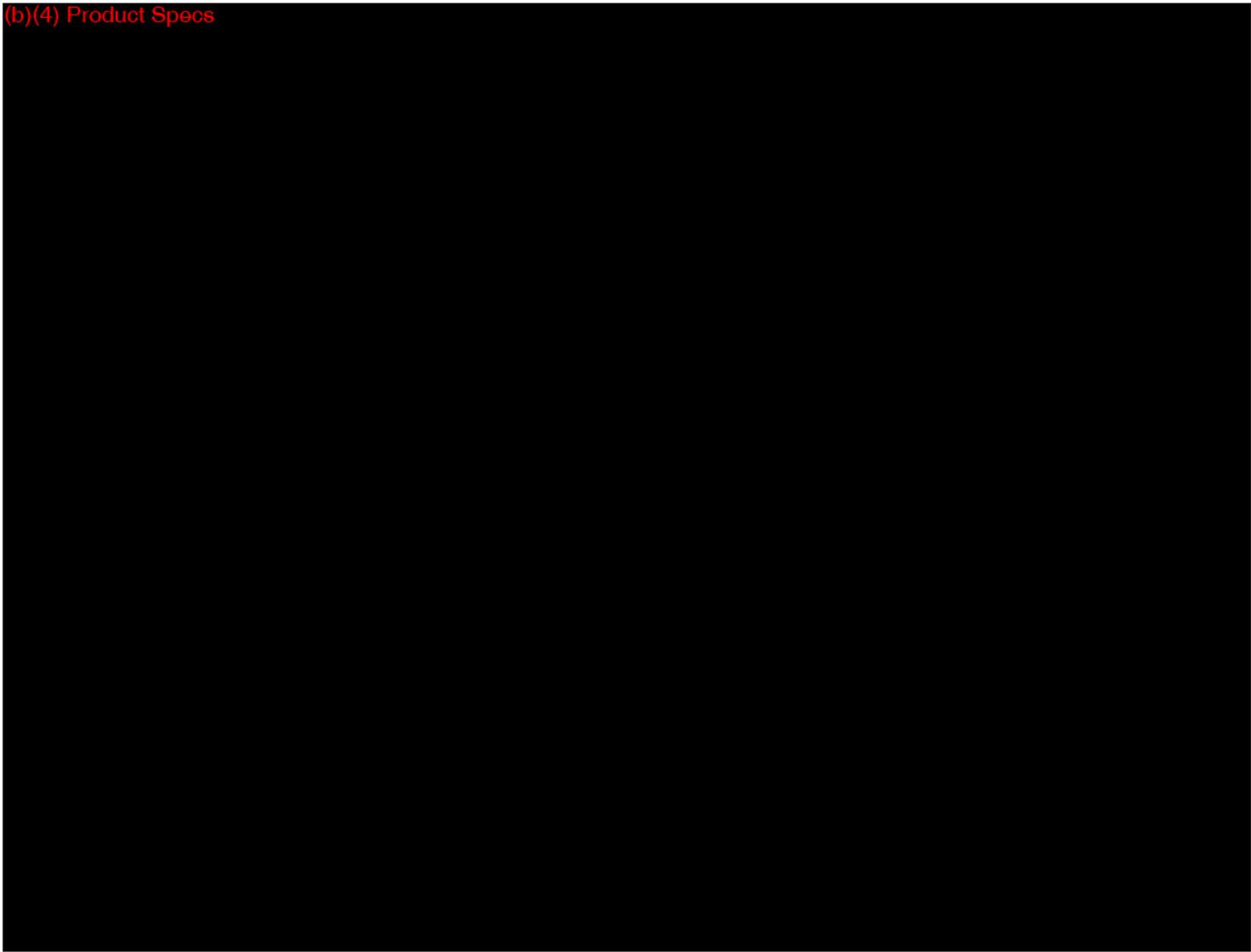


(b)(4) Product Specs





(b)(4) Product Specs



Lastly, per the FDA Device Advice *Content of a 510(k)* (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm>), we would like to exercise our option to replace the 510(k) Statement that was provided in Tab 5 of the original submittal with a 510(k) Summary, as the substantial equivalence determination has not yet been reached. Please see the 510(k) Summary included in Attachment 3.

If you should require any additional information, please contact me at 724-387-4146 (office), (b) [REDACTED] or by email at Michelle.Brinker@Philips.com. (6)

Thank you again for your review.

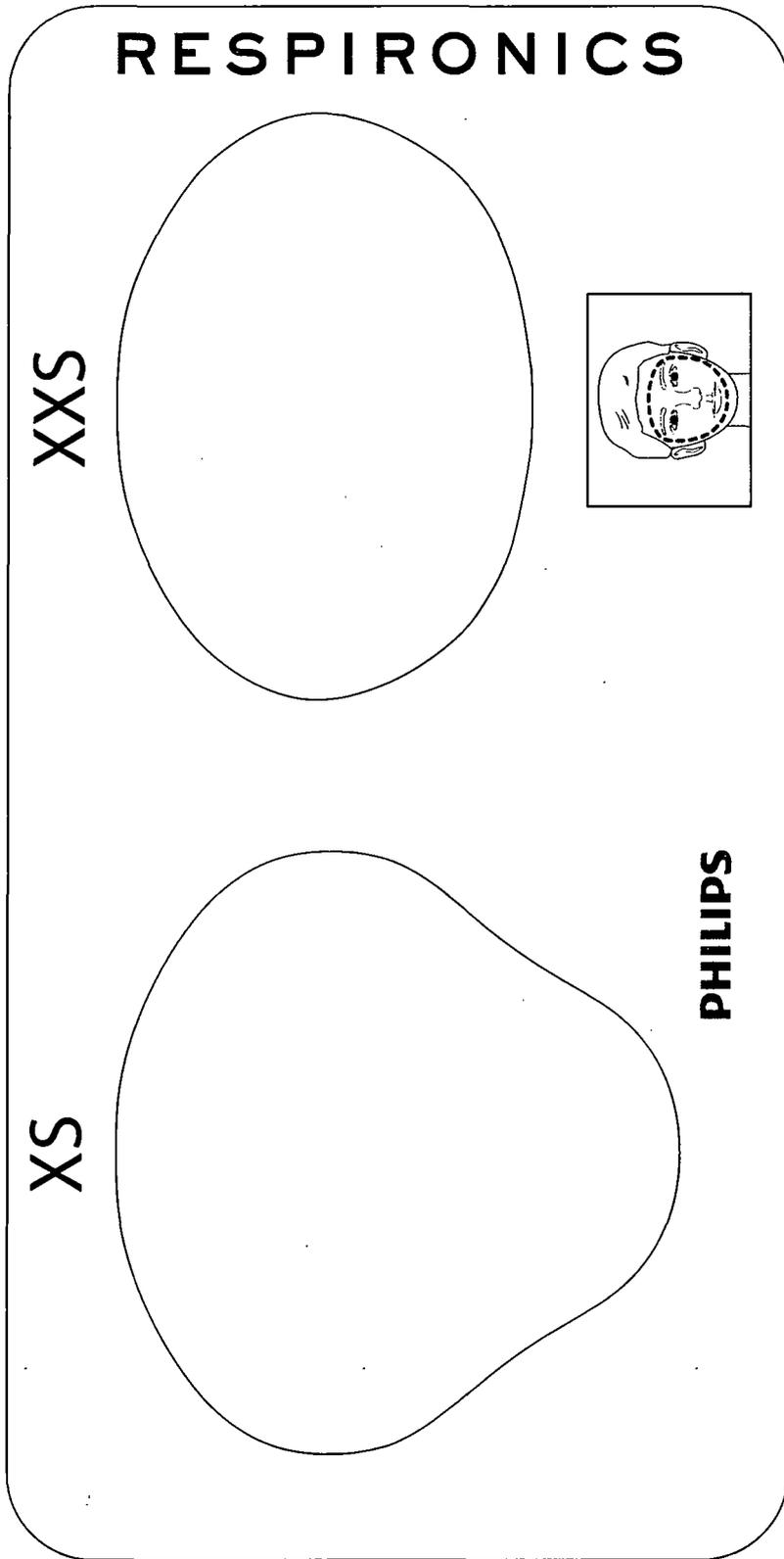
Sincerely,

(b) (6) [REDACTED]

Michelle Brinker
Regulatory Affairs Manager, Patient Interface

Attachment 1

Attachment 2



Attachment 3

TAB 5

510(K) SUMMARY

Date of Submission	21 February 2012
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-4146 (724) 387-3999 (fax)
Official Contact	Michelle Brinker Regulatory Affairs Manager, Patient Interface
Proprietary Name	PerforMax Pediatric EE Total Face Mask
Common/Usual Name	Face Mask
Classification Name / Product Code	BZD – Ventilator, Non-Continuous (Respirator)
Predicate Device(s)	Respironics PerforMax Youth EE Total Face Mask (K092043) Respironics Small Child Profile Lite Nasal Mask (K093416)

Device Description

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. It provides a seal such that positive pressure from the positive pressure source is directed into the patient's nose and mouth. It is held in place with an adjustable bonnet headgear. It may be cleaned by the professional in the hospital/institutional environment through a thermal high-level disinfection process or a chemical high-level disinfection process for multi-patient use.

The PerforMax Pediatric EE Total Face Mask consists of a faceplate with a bonded silicone seal for the face and an elbow with an integral entrainment valve. The mask features an interchangeable elbow hub which accepts an EE Leak 1 and EE Leak 2 elbow. The EE Leak 2 elbow includes built-in exhalation, an entrainment valve, a flexible tube, and a 22 mm connection. The EE Leak 1 elbow includes an entrainment valve and a 22 mm connection. The 22 mm elbow is used to connect a conventional air delivery hose between the mask and the positive airway pressure source. The bonnet headgear is

connected to the mask through slots in the upper part of the frame and clips that attach to the lower part of the frame. The mask is designed in such a way that it can be easily disassembled for disinfection or to replace several of the mask components, such as the headgear and elbow.

Intended Use

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Summary of Technological Characteristics of Device Compared to the Predicate Devices

The PerforMax Pediatric EE Total Face Mask has the following similarities in the technological characteristics to the previously cleared devices (Respironics PerforMax Youth EE Total Face Mask, K092043, and Respironics Small Child Profile Lite Nasal Mask, K093416):

1. Same intended use
2. Same operating principle
3. Same technology
4. Similar device design
5. Similar physical properties
6. Similar materials used
7. Same scientific concepts that form the basis for the device

The PerforMax Pediatric EE Total Face Mask has the following differences in the technological characteristics to the previously cleared devices (Respironics PerforMax Youth EE Total Face Mask, K092043, and Respironics Small Child Profile Lite Nasal Mask, K093416):

1. Faceplate and cushion have been reduced in size.
2. Elbow modified
3. Operating pressure range has been modified.
4. Addition of inspiratory and expiratory resistance performance specification.
5. Mask leak specifications has been modified.
6. The elbow body, elbow hub, and headgear materials have been modified.

Summary of the Non-Clinical Test Submitted, Referenced or Relied on in the 510(k)

To demonstrate performance and functionality was unaffected as a result of these changes, extensive performance testing was completed. Testing was performed pre and post hospital/institutional cleaning and disinfection treatments. Additionally, the mask was tested for high level disinfection in accordance with AAMI TIR No. 12-2004, AAMI TIR 30-2003, ASTM E1837-96 (2007), and the “Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants” – FDA CDRH, January 3, 2000. All patient contacting or gas path materials used in the mask have been previously cleared by the FDA or evaluated in accordance with the guidance provided by ISO 10993-1.

Results from this testing demonstrate that the PerforMax Pediatric EE Total Face Mask meets its performance specifications, raises no new issues of safety or effectiveness, and is substantially equivalent to the identified device predicates.

Clinical Data

Use of face masks with CPAP or bi-level therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the PerforMax Pediatric EE Total Face Mask, as was the case with the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

K120562/S3 V1

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

Ms. Michelle Brinker
Regulatory Affairs Manager, Patient Interface
Respironics, Incorporated
Sleep and Home Respiratory Group
365 Plum Industrial Court
Pittsburg, Pennsylvania 15239

JUL 17 2012

Re: K120562

Trade/Device Name: PerforMax Pediatric EE Total Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 9, 2012
Received: July 10, 2012

Dear Ms. Brinker:

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.

Page 2 - Ms. Brinker

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

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

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

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K120562

Device Name: PerforMax Pediatric EE Total Face Mask

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120562



COVER SHEET MEMORANDUM

From: Reviewer Name James Lee
Subject: 510(k) Number K120562/S3
To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

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?			X
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/CO-MBINATION%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)?			✓
For United States-based clinical studies only : Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, 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.)

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 868.5905

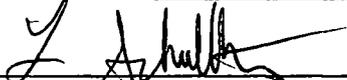
II

B2D

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

Additional Product Codes:

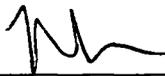
Review:


(Branch Chief)

ARDD
(Branch Code)

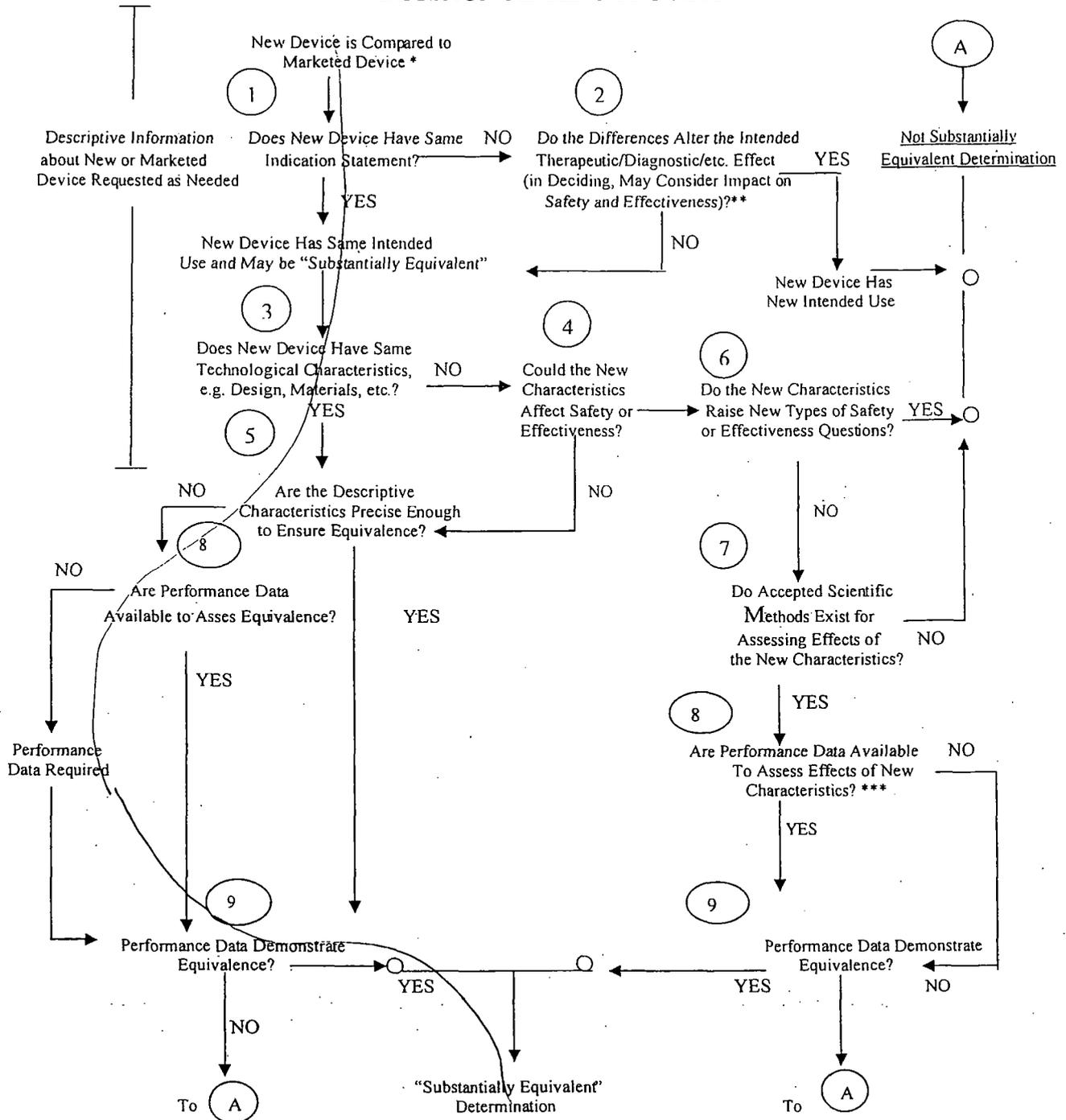
7/16/12
(Date)

Final Review:


(Division Director)

7/17/12
(Date)

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.



Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K120562/S003

Date: July 13, 2012
To: The Record
From: James Lee PhD
510(k) Holder: RESPIRONICS INC
Device Name: Performax Pediatric EE Total Face Mask
Contact: Michelle Brinker
Phone: (724) 387-4146
Fax: (724) 387-3999
Email: michelle.brinker@philips.com

Office:
Division: DAGID/ARDB

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the Respiroics Performax Pediatric EE Total Face Mask into interstate commerce. The Performax Pediatric EE Total Face Mask is a modification in design to the Respiroics Performax Youth EE Total Face Mask (previously cleared under K092043) and Respiroics Small Child Profile Lite Nasal Mask (previously cleared under K093416). The modifications consist of the following:

1. Updated environment to restrict to hospital/institutional use only
2. Reduced size of the faceplate and cushion
3. Modified elbow
4. Modified the mask operating pressure range, replaced unintentional leak specification with total mask leak specification, and added inspiratory and expiratory resistance specification
5. Material changes for the elbow hub, elbow body, and headgear

The modified device is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The Performax Pediatric EE Total Face Mask is for patients 1 year or older (> 7 kg). The mask is for multi-patient use in the hospital / institutional environment only.

Reviewer Comment: After multiple requests for additional information, this reviewer recommends that this submission should be found to be Substantially Equivalent to the predicate.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC) Provided in Section 4	X		
Truthful and Accuracy Statement Provided in Section 6p	X		
510(k) Summary or 510(k) Statement Provided in Section 5	X		
Standards Form	x		

510(k) Summary

The sponsor has provided its 510(k) Summary in Section 5.

Required Elements for 510(k) Summary (21 CFR 807.92)		
	Clearly labeled "510(k) Summary"	yes
	Submitter's name, address, phone #, a contact person	yes
	Date the summary was prepared	yes
	The name of the device/trade name/common name/classification name	yes
	An identification of the legally marketed predicate	yes
	Description of the subject device	yes
	Statement of intended use	yes
Technological characters	if same, a summary of comparison of technological characters	yes
	If different, a summary of how do they compare to the predicate	
Performance Data	Brief discussion of non-clinical data submitted, referenced, or relied on	yes
	Brief discussion of clinical data submitted, referenced, or relied on, including: <ul style="list-style-type: none"> - Description upon whom the device was tested, - Data obtained from the tests and especially: <ul style="list-style-type: none"> ▪ Adverse events and complications ▪ Other information for SE determination 	
	Conclusion that data demonstrate SE	
Required Elements for 510(k) Statement (21 CFR 807.93)		N/A
	Signed verbatim statement	

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?			

The Performax Pediatric EE Total Face Mask expands upon the existing Respiration Performax product line, which currently includes a size cleared for patients 7 years and older (> 18.2 kg).

The PerforMax Pediatric EE Total Face Mask consists of a (b) (4) faceplate, a silicone cushion that seals along the perimeter of the face, an elbow with an integral entrainment valve, and an elbow hub that retains the elbow. A pressure-pick off port is located on the elbow body. The mask is secured to the head with a bonnet style headgear.

The PerforMax elbow hub allows the medical professional to use the mask with either an Entrainment Elbow (EE) Leak 2 or an Entrainment Elbow (EE) Leak 1. The EE Elbow is a simple press fit assembly into the hub of the mask.

Both the EE Leak 2 and EE Leak 1 elbows have an entrainment valve opening which provides fresh air and flushes exhaust air in the event of a single fault condition, such as non-operational therapy device.

The EE Leak 2 elbow has built-in exhalation flutes along the entrainment valve. A separate exhalation device is not required with the EE Leak 2 elbow. The EE Leak 1 elbow does not have built-in exhalation. A separate exhalation device is required with the EE Leak 1 elbow.

The EE Leak 2 elbow has a 6" fixed 15 mm to 22 mm flexible extension tube attached. There is a 22 mm swivel connector at the end of the tubing to attach to standard 22 mm tubing used with CPAP and bi-level systems. The EE Leak 1 elbow connects directly to standard 22 mm tubing used with CPAP and bi-level systems (see Figure 3). The EE Leak 1 elbow does not include an extension tube or swivel. The PerforMax Pediatric EE Total Face Mask is available in two sizes, XS and XXS.

IV. Indications for Use

Indications for Use as provided in Section 4 of the original submission:

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bilevel system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Prescription Use has been indicated.

Predicate Indications for Use:

PerforMax Youth EE Total Face Mask (K092043) –

The Respirationics BiPAP Synchrony 2 is intended to provide non-invasive ventilation for pediatric patients 7 years or older (> 40 lbs) or adult patients (> 66 lbs) with respiratory insufficiency or obstructive sleep apnea, in the hospital or home.

Small Child Profile Lite Nasal Mask (K093416) –

The Respirationics Trilogy200 system provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Trilogy200 is intended for pediatric through adult patients weighing at least 5 kg (11 lbs.).

The device is intended to be used in home, institution/hospital, and portable applications such as wheelchairs and gurneys, and may be used for both invasive and non-invasive ventilation

(b) (4)

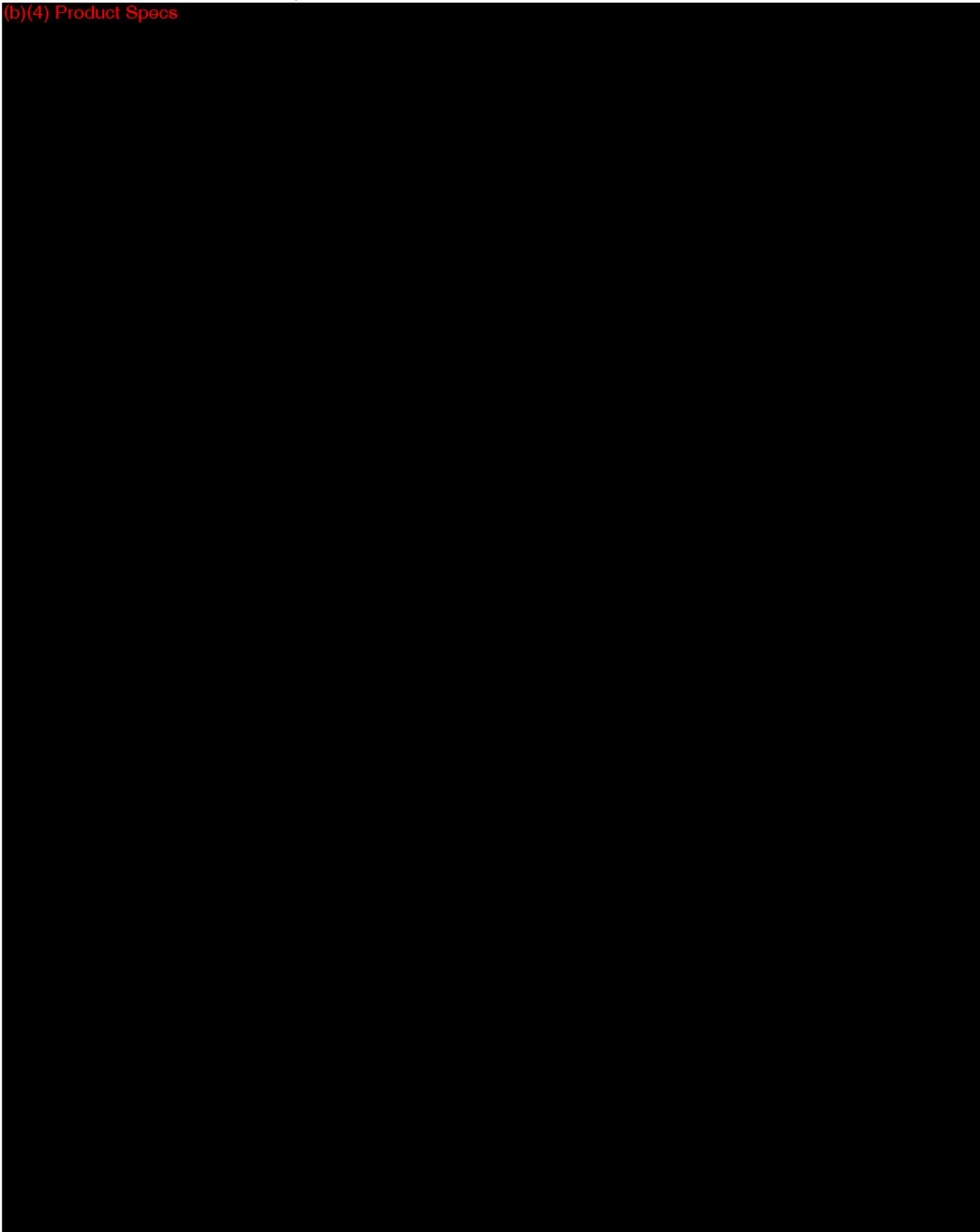
V. Predicate Device Comparison

(b) (4)

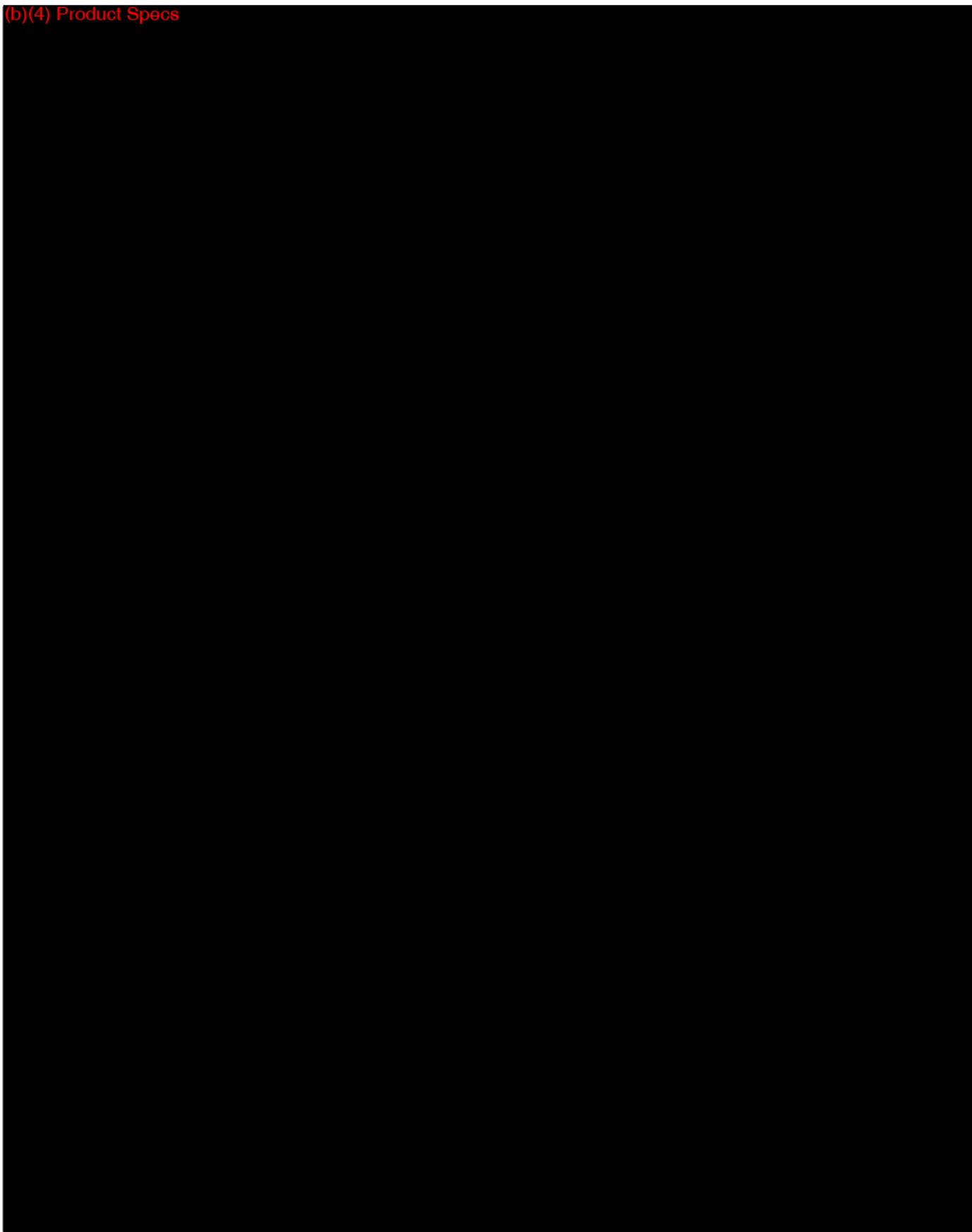
The following table compares the submitted device with the primary and secondary predicates.

	Primary Predicate Device: PerforMax Youth EE Total Face Mask Manufacturer: Respironics, Inc. 510(k) Number: K092043	Secondary Predicate Device: Small Child Profile Lite Nasal Mask Manufacturer: Respironics, Inc. 510(k) Number: K093416	Subject Device: PerforMax Pediatric EE Total Face Mask Manufacturer: Respironics, Inc. 510(k) Number: To be determined
Intended Use submitted in labeling	The PerforMax Youth EE Total Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients.	The Small Child Profile Lite Nasal Mask and Softcap are intended to provide an interface when used with CPAP or bi-level therapy.	Similar to K092043 and K093416 PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system.
<i>Patient Population</i>	7 years or older (> 18.2 kg)	1 year or older (> 7 kg)	Unchanged from K093416
<i>Environment of Use of the System</i>	Home or Hospital/institutional	Home or hospital/institutional	Hospital/institutional only
<i>Patient Usage Type</i>	Single Patient use in the home and Multi-patient use in the hospital/institutional environment	Single Patient Use	Unchanged from K092043 in the Hospital/institutional environment
<i>Product Code</i>	MNS	CBK	BZD
<i>Provided Sterile or Non-Sterile</i>	Provided clean, not sterile	Provided clean, not sterile	Unchanged from K093416/K092043
<i>Anatomical Sites</i>	Total Face Mask, covering the eyes, nose and mouth	Nasal interface, covering only the nose	Unchanged from K092043

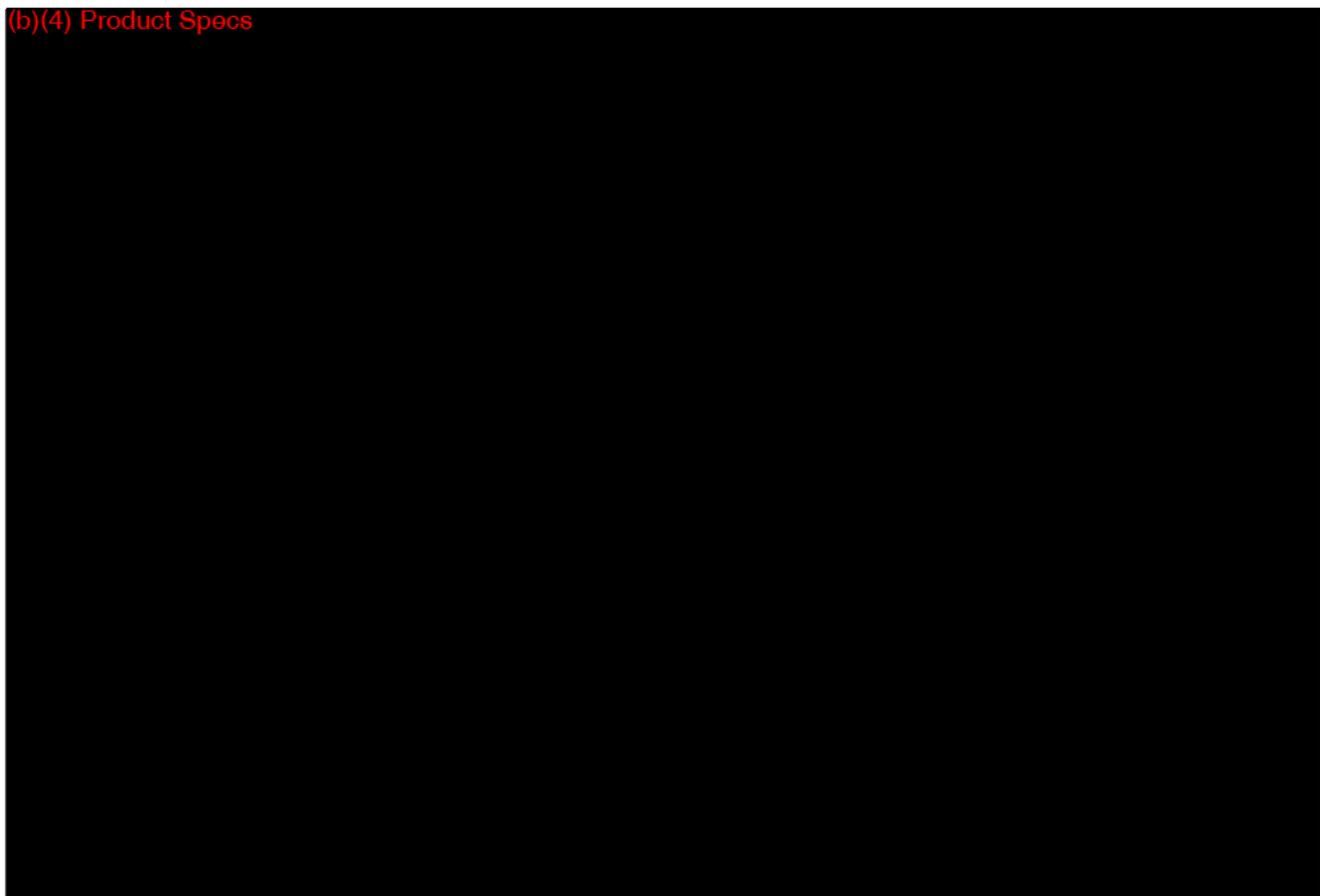
(b)(4) Product Specs



(b)(4) Product Specs



(b)(4) Product Specs

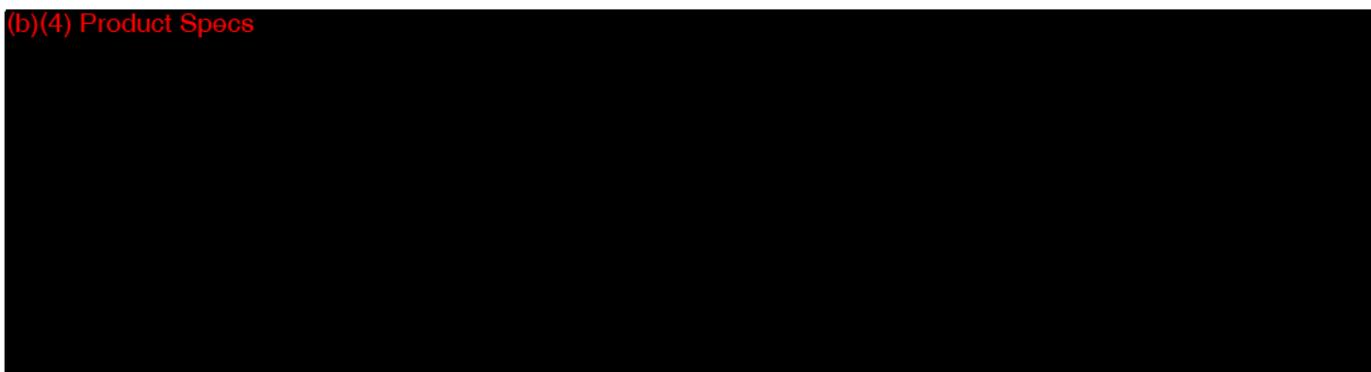


(b) (4)



VI. Labeling

(b)(4) Product Specs



VII. Sterilization/Shelf Life/Reuse

(b)(4) Product Specs



AAMI TIR No.12-2004, Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for the Device Manufacturer, 23 December 2004

AAMI TIR No. 30-2003, A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices, 8 October 2003

ASTM E1837-96 (Re-approved 2002), Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test), Oct. 10, 1996

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories

VIII. Biocompatibility

A skin contacting and gas pathway materials have been evaluated in accordance with the guidance provided in ISO-10993-1. A declaration of conformity to ISO-10993-1 is provided in Tab 9 of the original submission.

Tab 9A	Declaration of Conformity to ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process <i>Includes summary materials table and exploded assembly diagrams</i>
	FORM FDA 3654 Standards Data Report for 510(k)s – ISO 10993-1:2009
	Summary Report for ISO 10993-1:2009
Tab 15A	Biocompatibility Report (b) (4)
Tab 15B	Biocompatibility Report (b) (4)
Tab 15C	Biocompatibility Report (b) (4)

IX. Software

This device has no software, this section is not applicable.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The device has not electrical or mechanical systems, this section is not applicable.

XI. Performance Testing – Bench

The following is a summary of the bench testing that was performed on the Performax Pediatric EE Total Face Mask.

Mask Performance Testing

- Mask Deadspace
- Pressure Drop
- Total Mask Leak (TML)
- Intentional Leak
- Inspiratory and expiratory resistance – Anti-asphyxia valve open to atmosphere
- Anti-asphyxia valve closing to atmosphere and Anti-asphyxia valve opening to atmosphere
- CO2 Flow Dissipation Test

System Testing

- Alarms (Patient Disconnect, Apnea, Low Minute Ventilation, High Minute Ventilation, Low Respiratory Rate, High Respiratory Rate, Low Exhaled Tidal Volume, and High Exhaled Tidal Volume)
- Triggering Sensitivity
- Triggering Stability
- Patient Triggering Waveform Performance Data
- Mandatory Ventilation Waveform Performance Data

Environmental Testing

Per the guidance in the FDA Reviewer Guidance for Premarket Notification Submissions, November 1993, testing will be performed to demonstrate safety and effectiveness of the performance characteristics of the device in the intended environment of use and post-storage conditioning. The Intent to Declare Conformance is provided in Tab 9C and test matrix per Appendix A of FDA Reviewer Guidance for Premarket Notification Submissions, November 1993, is provided in Tab 18B.

Risk Assessment

An initial hazards assessment was performed for the PerforMax Pediatric EE Total Face Mask. The assessment analyzed the use situation, the sequence of events, and harm. An initial risk level of the harm was established based on the initial severity and probability classifications (as defined in the risk management plan in Tab 18C).

XII. Performance Testing – Animal

N/A Animal testing not needed to determine substantial equivalence.

XIII. Performance Testing – Clinical

N/A Clinical testing was not submitted to determine substantial equivalence. Submission only has a reference to a clinical study performed in 2000.

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?	x	If YES = Stop NSE
3. Same Technological Characteristics?	x	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	x	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?	x	If YES = Stop NSE
7. Accepted Scientific Methods Exist?	x	If NO = Stop NSE
8. Performance Data Available?	x	If NO = Request Data
9. Data Demonstrate Equivalence?	x	Final Decision: SE

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. 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:
Additional information regarding the verification and validation activities is needed in order to determine substantial equivalence.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not 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:

The Total mask leak for the subject devices (which the sum of unintentional and intentional leak) demonstrates substantial equivalence to the predicate. The sponsor has made measurements of flow rates at varying pressures of the subject devices which are to be substantially equivalent to the Performax Youth Mask. Plots for flow rates vs. pressure indicate that the subject and predicate devices are well aligned.

XVII. Recommendation

I recommend that the subject device is Substantially Equivalent to the predicates after the receipt of additional information from the sponsor.

Regulation Number: 21 CFR 868.5905
Regulation Name: Nasal Mask
Regulatory Class: Class II
Product Code: BZD



James Lee PhD, Lead Reviewer


Lex Schultheis, MD, PhD, ARDB Branch Chief

7.13.12

Date
7/16/12

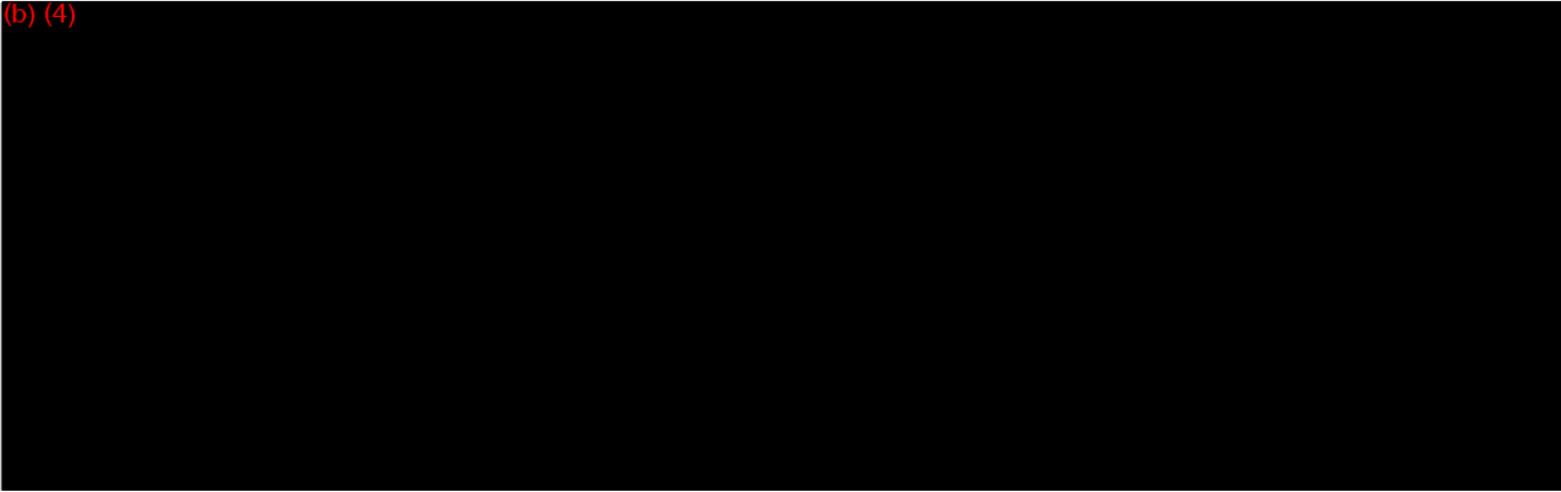
Date

Lee, James J (CDRH)

From: Lee, James J (CDRH)
Sent: Tuesday, July 17, 2012 4:00 PM
To: Samuels-Reid, Joy H.
Cc: Schultheis, Lester
Subject: RE: Question regarding Pediatric IFUs

Dear Joy

(b) (4)



Many thanks again
James

From: Samuels-Reid, Joy H.
Sent: Tuesday, July 17, 2012 3:42 PM
To: Lee, James J (CDRH)
Subject: RE: Question regarding Pediatric IFUs

(b) (4)



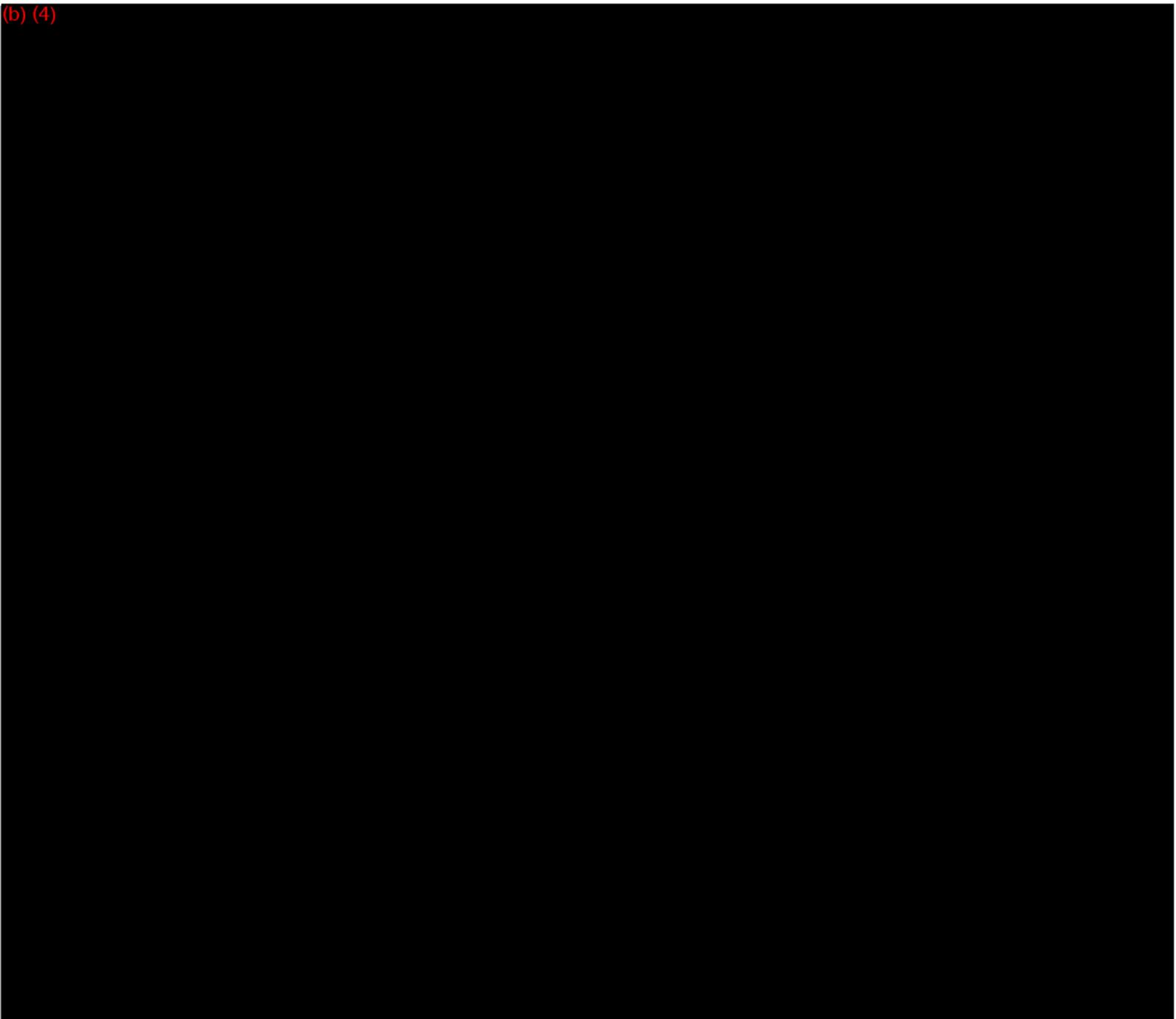
Joy

Joy Samuels-Reid, M.D., FAAP
Chief Medical Officer,
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Center for Devices and Radiological Health
US Food and Drug Administration
Office of Device Evaluation-White Oak - Bldg 66-2608
10903 New Hampshire Avenue, Silver Spring,
Maryland, 20993
Tel: 301-796-5580
Fax: 301-847-8109
Joy.Samuels-Reid@fda.hhs.gov

From: Lee, James J (CDRH)
Sent: Tuesday, July 17, 2012 3:07 PM
To: Samuels-Reid, Joy H.
Cc: Schultheis, Lester
Subject: Question regarding Pediatric IFUs

Dear Dr. Samuels-Reid

(b) (4)



James Lee Ph.D.
Interdisciplinary Scientist, Biomedical Engineer
DA/ODE/CDRH/DAGID/ARDB
10903 New Hampshire Ave.
Silver Spring, MD 20993
WO66, Rm. 1544
james.j.lee@fda.hhs.gov
(301) 796-8463

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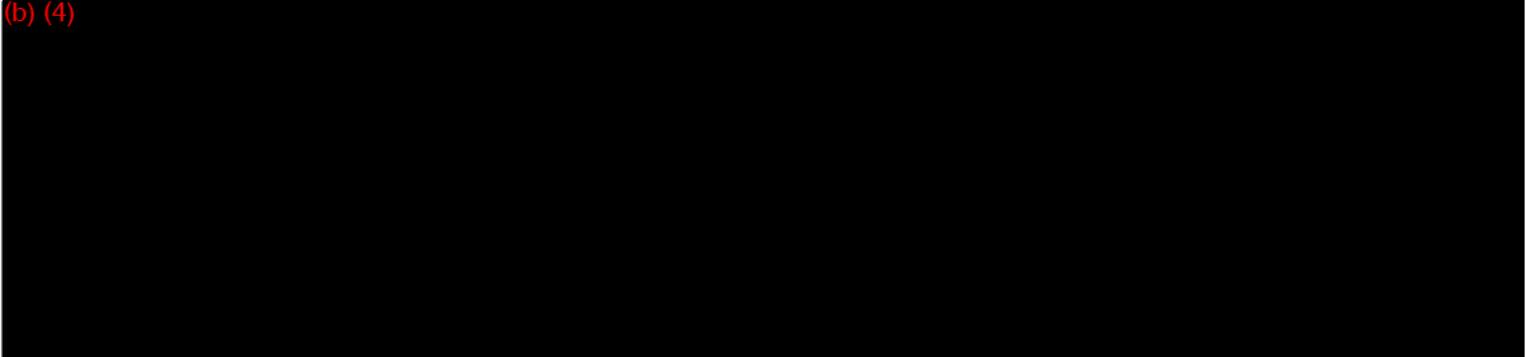
This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

Lee, James J (CDRH)

From: Brinker, Michelle <michelle.brinker@philips.com>
Sent: Thursday, July 12, 2012 5:06 PM
To: Lee, James J (CDRH)
Subject: RE: K120562 Performax Pediatric
Attachments: Updated Instructions - PMax Pediatric EE Leak 2.pdf; Updated Instructions - PMax Pediatric EE Leak 1.pdf

Dear James,

(b) (4)



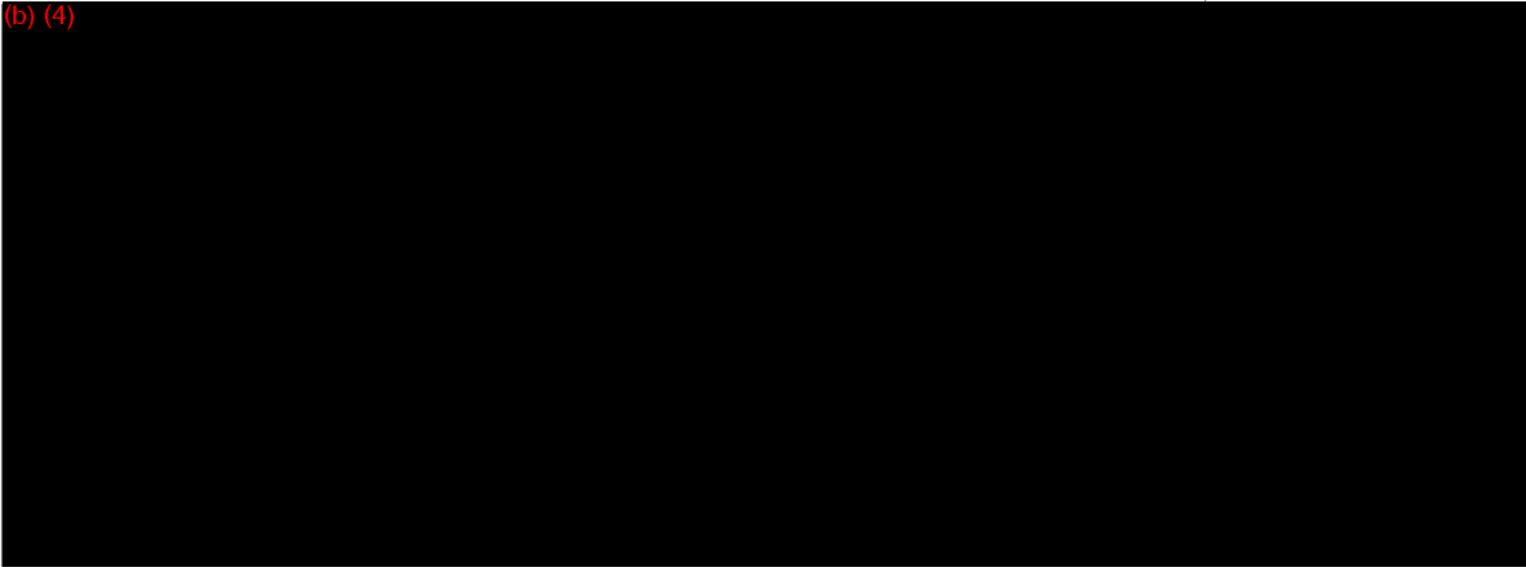
Michelle Brinker
Regulatory Affairs Manager, Patient Interface
Respironics, Inc.

c: 724-387-4146, c: (b) (6)
f: 724-387-3999

From: Lee, James J (CDRH) [<mailto:James.J.Lee@fda.hhs.gov>]
Sent: Thursday, July 12, 2012 10:51 AM
To: Brinker, Michelle
Subject: K120562 Performax Pediatric

Dear Michelle Brinker

(b) (4)



Thanks
James

James Lee Ph.D.
Interdisciplinary Scientist, Biomedical Engineer
FDA/ODE/CDRH/DAGID/ARDB
10903 New Hampshire Ave.
Silver Spring, MD 20993
WO66, Rm. 1544
james.j.lee@fda.hhs.gov
(301) 796-8463

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

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Intended Use

The Performax Pediatric Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital/institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Note: An exhalation port is not built into the mask. A separate exhalation device must be used with this mask.

Note: This mask is not made with natural rubber latex or DEHP.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Symbols

Warning or Caution Note Tip

Not made with natural rubber latex Leak Symbol and Value

Warnings

- Patients using this mask must remain under constant supervision by trained medical personnel.
- This mask is not suitable for providing life support ventilation.
- Hand wash prior to use. Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.
- This mask requires a separate exhalation device.
- This mask is designed for use with CPAP or bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly. Do not block or try to seal the exhalation port. Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.
- If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Explanation of the Warning: When the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.
- At low CPAP or EPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- Some patients may experience skin redness, irritation, or discomfort. If this happens, monitor and intervene.
- Monitor and intervene if any of the following symptoms occur: Unusual chest discomfort, shortness of breath, stomach distension, belching, severe headache, blurred vision, drying of the eyes, eye pain or eye infections.
- This mask is not recommended if the patient is taking a prescription drug that may cause vomiting.
- Monitor and intervene if the patient encounters tooth, gum or jaw soreness. Use of a mask may aggravate a patient's existing dental conditions.
- A minimum of 3cm H₂O pressure must be maintained when using this mask.
- The mask contains small parts which could result in a choking hazard.
- Attaching an exhalation device requires therapy pressure level adjustment to compensate for increased leak.
- Do not overtighten the headgear straps. Watch for signs of overtightening, such as excessive redness, bruises, sores or bulging around the edges of the mask. Loosen the headgear straps to alleviate symptoms.
- Do not block or seal off the anti-asphyxia valve.

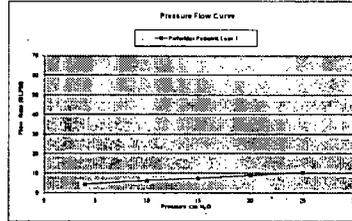
Contraindications

This mask may not be suitable for use on patients with the following conditions: glaucoma, recent eye surgery or dry eyes, impaired nictitation (blinking), hiatus hernia, impaired cardiac sphincter function, esophageal reflux, impaired cough reflex; or on patients who are not under constant, immediate observation by personnel experienced in noninvasive ventilation management.

Specifications

Warning: The technical specifications of the mask are provided to determine if it is compatible with your CPAP or bi-level therapy device. If used outside these specifications or if used with incompatible devices, the mask may be uncomfortable, the seal of the mask may not be effective, optimum therapy may not be achieved, and leak or variation in the rate of leak, may affect device function.

Pressure Flow Curve



Resistance with Anti-Asphyxia Valve Closed to Atmosphere Drop in Pressure at

	50 SLPM	100 SLPM
All sizes	0.4 cm H ₂ O	1.0 cm H ₂ O

Inspiratory and Expiratory Resistance with Anti-Asphyxia Valve Open to Atmosphere

Inspiratory Resistance	1.5 cm H ₂ O
Expiratory Resistance	0.8 cm H ₂ O

Deadspace

XXS	283 ml
XS	311 ml

Disposal

Dispose of in accordance with local regulations.

Storage Conditions

Temperature: -4° to 140° F (-20° to +60° C)
Relative Humidity: 15% to 95% non-condensing

RESPIRONICS

DRAFT Instructions for Use

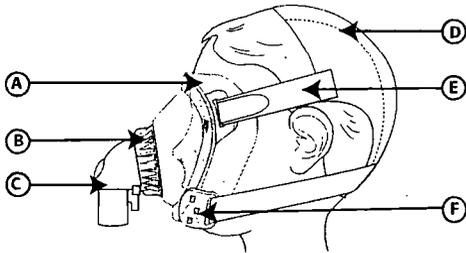
Performax Pediatric EE Leak 1 Total Face Mask



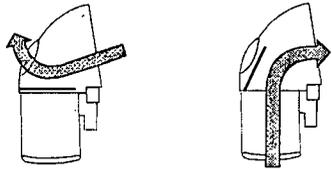
Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668 USA



Features



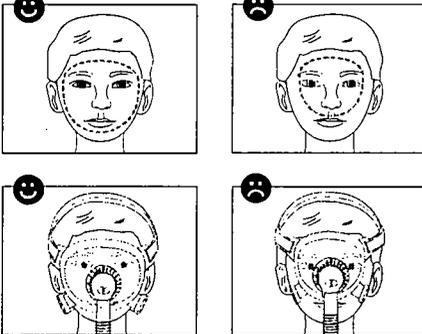
- A Mask Cushion
- B Faceplate Hub
- C Entrainment Elbow with Anti-Asphyxia Valve (Do not block)
- D Bonnet
- E Top Headgear Straps
- F Bottom Headgear Clips



2a

2b

Sizing the Mask



Verify the Anti-Asphyxia Valve

The anti-asphyxia valve consists of an air inlet and a flapper. With the airflow turned off, verify that the elbow with the flapper is lying flat (2a) so that room air can flow in and out through the air inlet. Next, with the airflow on, the flapper should now cover the air inlet and air from the CPAP or bi-level device should flow into the mask (2b). If the flapper does not close or does not function properly, replace.

Warning: Do not block or seal the anti-asphyxia valve.

Before Use Read and Understand the Instructions Completely

- Hand wash the mask.
- Wash the patient's face. Do not use moisturizer/lotion on your hands or the patient's face.
- Inspect the mask and replace it if the cushion has hardened or is torn, or if any parts are broken.
- Verify that the therapy device, i.e., ventilator, including the alarms and safety systems, has been validated prior to use.
- Verify therapy device pressure(s).

Pre-cleaning Instructions

Hand wash the mask before first use.

1. Hand wash mask in warm water with liquid dishwashing detergent or wipe with a 70% v/v isopropyl alcohol swab.

2. Rinse thoroughly. Air dry completely before use. Make sure the mask is dry before use.

Caution: Do not use bleach, cleaning solutions containing bleach, or cleaning solutions containing conditioners or moisturizers

Caution: Any deviation from these instructions may impact the performance of the product.

Caution: Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.

Institutional Disinfection

For multi-patient use in the hospital/institutional environment, use the Disinfection Guide to reprocess the mask between patients. These instructions can be obtained by visiting us online at www.philips.com/NIVmasks or by contacting customer service at 1-800-345-6443 or at 1-724-387-4000.

Leak Symbol and Port Settings

Some ventilators may incorporate the use of a leak symbol and value in the mask selection setup procedures. The leak characteristics of this mask is leak symbol (1). The leak symbol and value represents the intentional leak characteristics of the interface. On ventilators equipped with a Mask Selection control, enter the leak symbol value (1) that corresponds with the leak symbol value on the mask.

Comfort Tips

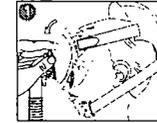
- The most common mistake is overtightening the headgear. The headgear should fit loose and comfortable. If the patient's skin bulges around the mask or if you see red marks on the patient's face, loosen the headgear.
- Adjust the top headgear straps to reduce leaks at the forehead and temples.
- Adjust the bottom headgear straps to reduce leaks at the sides of the patient's

PerforMax Interchangeable Leak 1 and Leak 2 Elbows

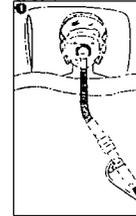
This mask may use the EE Leak 1 and EE Leak 2 elbows interchangeably. The clear EE Leak 1 elbow with an anti-asphyxia valve does not have built in exhalation. A separate exhalation device must be used with the EE Leak 1 elbow. The amber EE Leak 2 elbow with an anti-asphyxia valve includes exhalation. Refer to 2 of the Disassembly and Assembly of the Mask to change the elbow on the mask.

Achieving the Right Fit

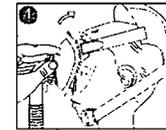
Applying the mask:



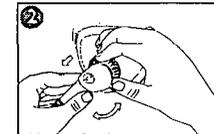
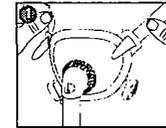
Using the mask:



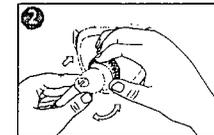
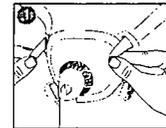
Removing the Mask:



Disassembly of the Mask:



Assembly of the Mask:



Intended Use

The PerformMax Pediatric Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital/institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Note: An exhalation port is built into the mask so a separate exhalation port is not required.

Note: This mask is not made with natural rubber latex or DEHP.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Symbols



Warning or Caution



Note



Tip



Not made with natural rubber latex



Leak Symbol and Value

Warnings

- Patients using this mask must remain under constant supervision by trained medical personnel.
- This mask is not suitable for providing life support ventilation.
- Hand wash prior to use. Inspect the mask for damage or wear (cracking, crazing, tears, etc.) Discard and replace any components as necessary.
- This mask is designed for use with CPAP or bi-level systems recommended by your health care professional or respiratory therapist. Do not wear this mask unless the CPAP or bi-level system is turned on and operating properly. Do not block or try to seal the exhalation port. Explanation of the Warning: CPAP systems are intended to be used with special masks with connectors which have vent holes to allow continuous flow of air out of the mask. When the CPAP machine is turned on and functioning properly, new air from the CPAP machine flushes the exhaled air out through the attached mask exhalation port. However, when the CPAP machine is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation. This warning applies to most models of CPAP systems.
- If oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. Explanation of the Warning: When the device is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the device enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection, and the leak rate. This warning applies to most types of CPAP and bi-level machines.
- At low CPAP or EPAP pressures the flow through the exhalation port may be inadequate to clear all exhaled gas from the tubing. Some rebreathing may occur.
- Some patients may experience skin redness, irritation, or discomfort. If this happens, monitor and intervene.
- Monitor and intervene if any of the following symptoms occur: Unusual chest discomfort, shortness of breath, stomach distension, belching, severe headache, blurred vision, drying of the eyes, eye pain or eye infections.
- This mask is not recommended if the patient is taking a prescription drug that may cause vomiting.
- Monitor and intervene if the patient encounters tooth, gum, or jaw soreness. Use of a mask may aggravate a patient's existing dental conditions.
- A minimum of 3cm H₂O pressure must be maintained when using this mask.
- The mask contains small parts which could result in a choking hazard.
- Attaching an exhalation device requires therapy pressure level adjustment to compensate for increased leak.
- Do not overtighten the headgear straps. Watch for signs of overtightening, such as excessive redness, bruises, sores or bulging skin around the edges of the mask. Loosen the headgear straps to alleviate symptoms.
- Do not block or seal off the anti-asphyxia valve.

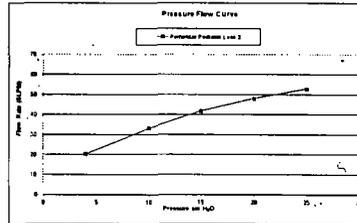
Contraindications

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Specifications

Warning: The technical specifications of the mask are provided to determine if it is compatible with your CPAP or bi-level therapy device. If used outside these specifications or if used with incompatible devices, the mask may be uncomfortable, the seal of the mask may not be effective, optimum therapy may not be achieved and leak, or variation in the rate of leak, may affect device function.

Pressure Flow Curve



Resistance with Anti-Asphyxia Valve Closed to Atmosphere

Drop in Pressure at

	50 SLPM	100 SLPM
All sizes	0.7 cm H ₂ O	2.1 cm H ₂ O

Inspiratory and Expiratory Resistance with Anti-Asphyxia Valve Open to Atmosphere

Inspiratory Resistance	1.2 cm H ₂ O
Expiratory Resistance	0.7 cm H ₂ O

Deadspace

XXS	255 mL
XS	284 mL

Disposal

Dispose of in accordance with local regulations.

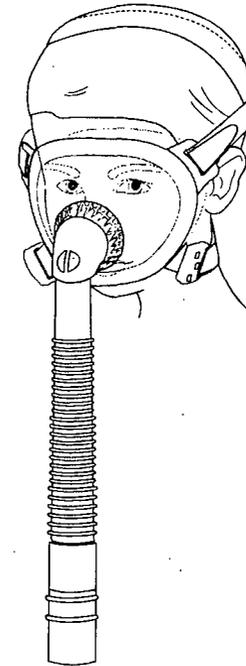
Storage Conditions

Temperature: -4° to 140° F (-20° to +60° C)
Relative Humidity: 15% to 95% non-condensing

RESPIRONICS

DRAFT Instructions for Use

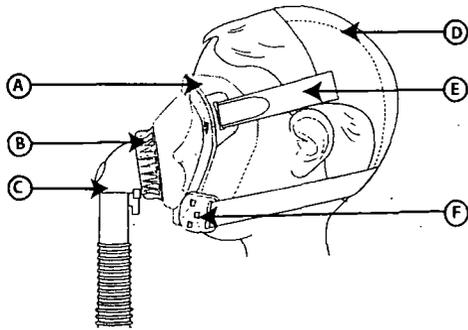
PerformMax Pediatric EE Leak 2 Total Face Mask



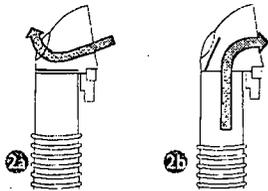
Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668 USA



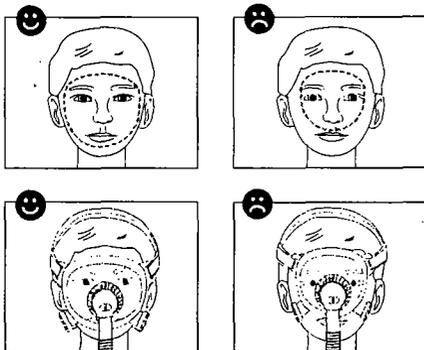
Features



- A Mask Cushion
- B Faceplate Hub
- C Entrainment Elbow with Anti-Asphyxia Valve and Exhalation (Do not block)
- D Bonnet
- E Top Headgear Straps
- F Bottom Headgear Clips



Sizing the Mask



Verify the Anti-Asphyxia Valve

The anti-asphyxia valve consists of an air inlet and a flapper. With the airflow turned off, verify that the elbow with the flapper is lying flat ^{2a} so that room air can flow in and out through the air inlet. Next, with the airflow on, the flapper should now cover the air inlet and air from the CPAP or bi-level device should flow into the mask. ^{2b} If the flapper does not close or does not function properly, replace.

Warning: Do not block or seal the anti-asphyxia valve.

Before Use Read and Understand the Instructions Completely

- Hand wash the mask.
- Wash the patient's face. Do not use moisturizer/lotion on your hands or the patient's face.
- Inspect the mask and replace it if the cushion has hardened or is torn, or if any parts are broken.
- Verify that the therapy device, i.e., ventilator, including the alarms and safety systems, has been validated prior to use.
- Verify therapy device pressure(s).

Pre-cleaning Instructions

Hand wash the mask before first use.

1. Hand wash mask in warm water with liquid dishwashing detergent or wipe with a 70% v/v isopropyl alcohol swab.

2. Rinse thoroughly. Air dry completely before use. Make sure the mask is dry before use.

Caution: Do not use bleach, cleaning solutions containing bleach, or cleaning solutions containing conditioners or moisturizers.

Caution: Any deviation from these instructions may impact the performance of the product.

Caution: Inspect the mask for damage or wear (cracking, crazing, tears, etc). Discard and replace any components as necessary.

Institutional Disinfection

For multi-patient use in the hospital/institutional environment, use the Disinfection Guide to reprocess the mask between patients. These instructions can be obtained by visiting us online at www.philips.com/NIVmasks or by contacting customer service at 1-800-345-6443 or at 1-724-387-4000.

Leak Symbol and Port Settings

Some ventilators may incorporate the use of a leak symbol and value in the mask selection setup procedures. The leak characteristics of this mask is leak symbol ¹ (2). The leak symbol and value represents the intentional leak characteristics of the interface. On ventilators equipped with a Mask Selection control, enter the leak symbol value ¹ (2) that corresponds with the leak symbol value on the mask.

Comfort Tips

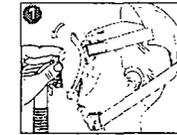
- The most common mistake is overtightening the headgear. The headgear should fit loose and comfortable. If the patient's skin bulges around the mask or if you see red marks on the patient's face, loosen the headgear.
- Adjust the top headgear straps to reduce leaks at the forehead and temples.
- Adjust the bottom headgear straps to reduce leaks at the sides of the patient's mouth.

PerforMax Interchangeable Leak 1 and Leak 2 Elbows

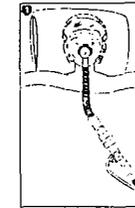
This mask may use the EE Leak 1 and EE Leak 2 elbows interchangeably. The clear EE Leak 1 elbow with an anti-asphyxia valve does not have built in exhalation. A separate exhalation device must be used with the EE Leak 1 elbow. The amber EE Leak 2 elbow with an anti-asphyxia valve includes exhalation. Refer to ² of the Disassembly and Assembly of the Mask to change the elbow on the mask.

Achieving the Right Fit

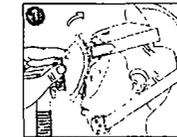
Applying the mask:



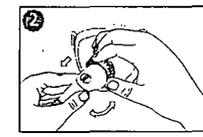
Using the Mask:



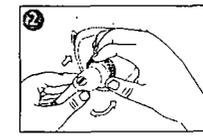
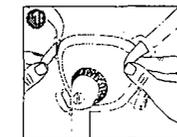
Removing the Mask:



Disassembly of the Mask:



Assembly of the Mask:





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

July 10, 2012

RESPIRONICS, INC.
SLEEP AND HOME RESPIRATORY GROUP
365 PLUM INDUSTRIAL COURT
PITTSBURGH, PENNSYLVANIA 15239
ATTN: MICHELLE BRINKER

510k Number: K120562

Product: PERFORMAX PEDIATRIC EE TOTAL F

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff

Mcdonald, Lisa *

From: Microsoft Outlook
To: michelle.brinker@philips.com
Sent: Tuesday, July 10, 2012 11:18 AM
Subject: Relayed: K120562 AI Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

michelle.brinker@philips.com

Subject: K120562 AI Letter

Sent by Microsoft Exchange Server 2007

K120562/S3

July 9, 2012

ATTN: Mr. James Lee, Ph.D.
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA/CDRH/DCC

JUL 10 2012

RECEIVED

K34

RE: K120562 – PerforMax Pediatric EE Total Face Mask

Dear Mr. Lee:

Thank you for your review of the Respironics, Inc. PerforMax Pediatric EE Total Face Mask submission. In response to your email sent on June 21, 2012, we are providing the following information.

(b) (4)



Thank you again for your review.

Sincerely,

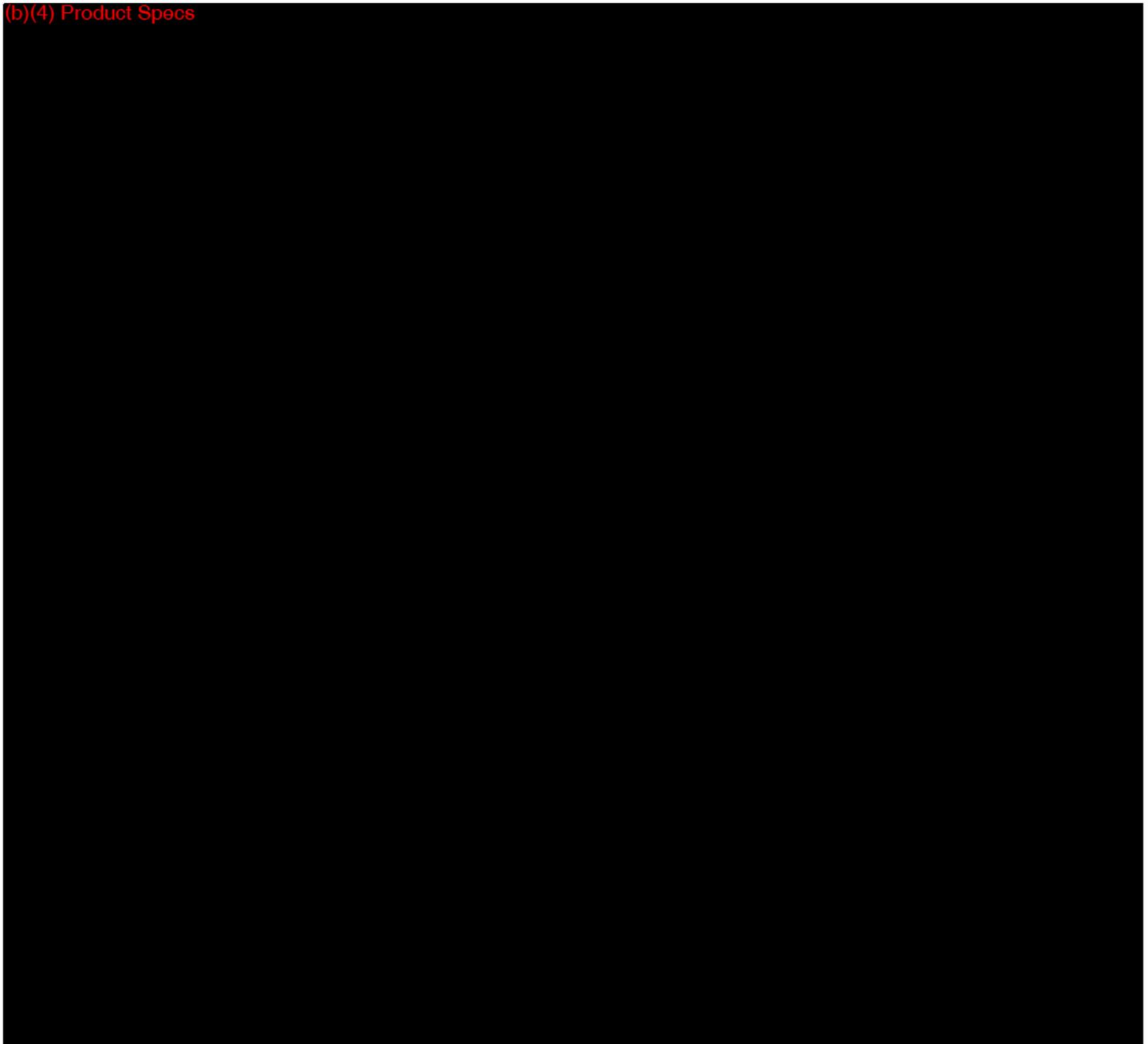
(b) (6)



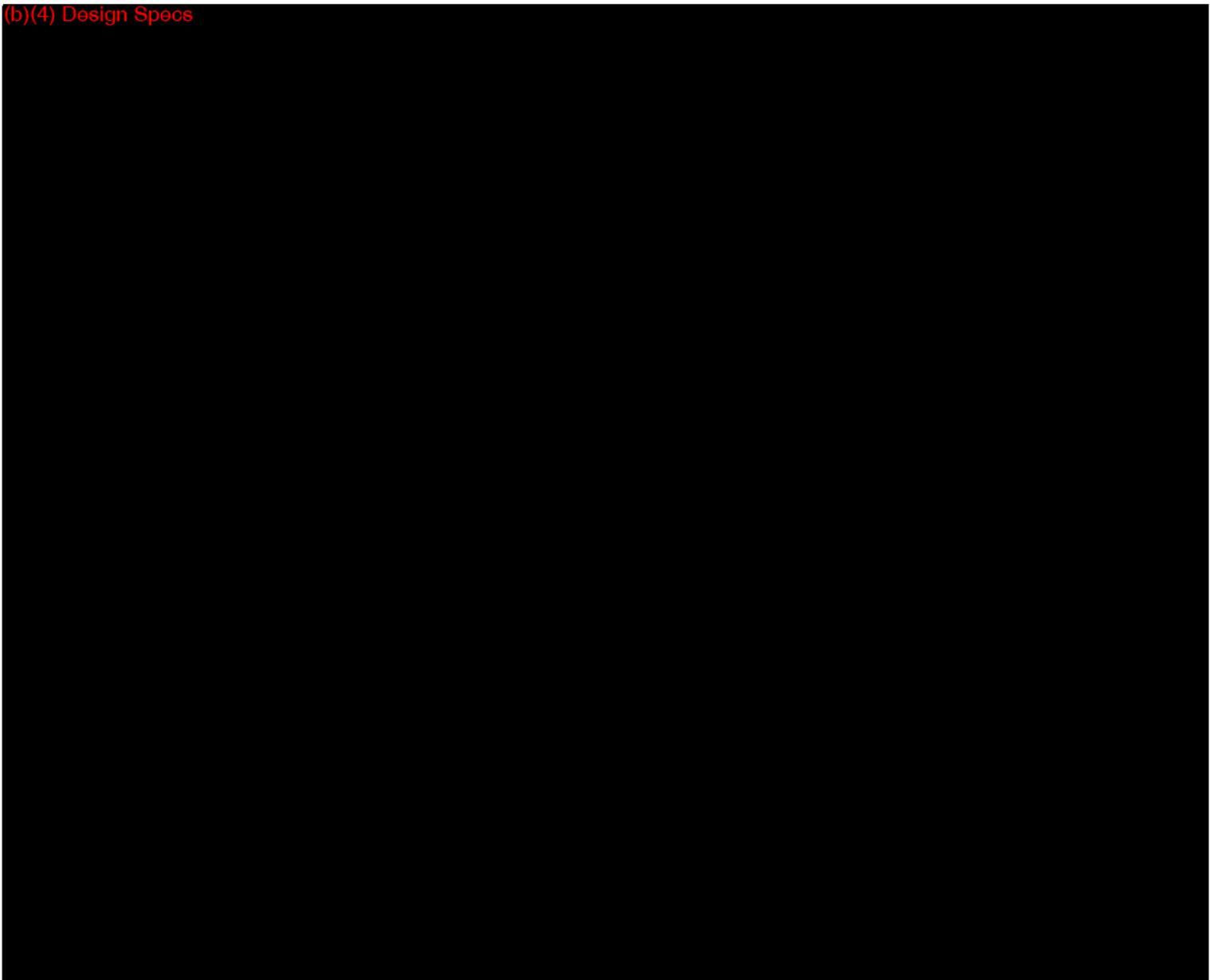
Michelle Brinker
Regulatory Affairs Manager, Patient Interface

Attachment 1

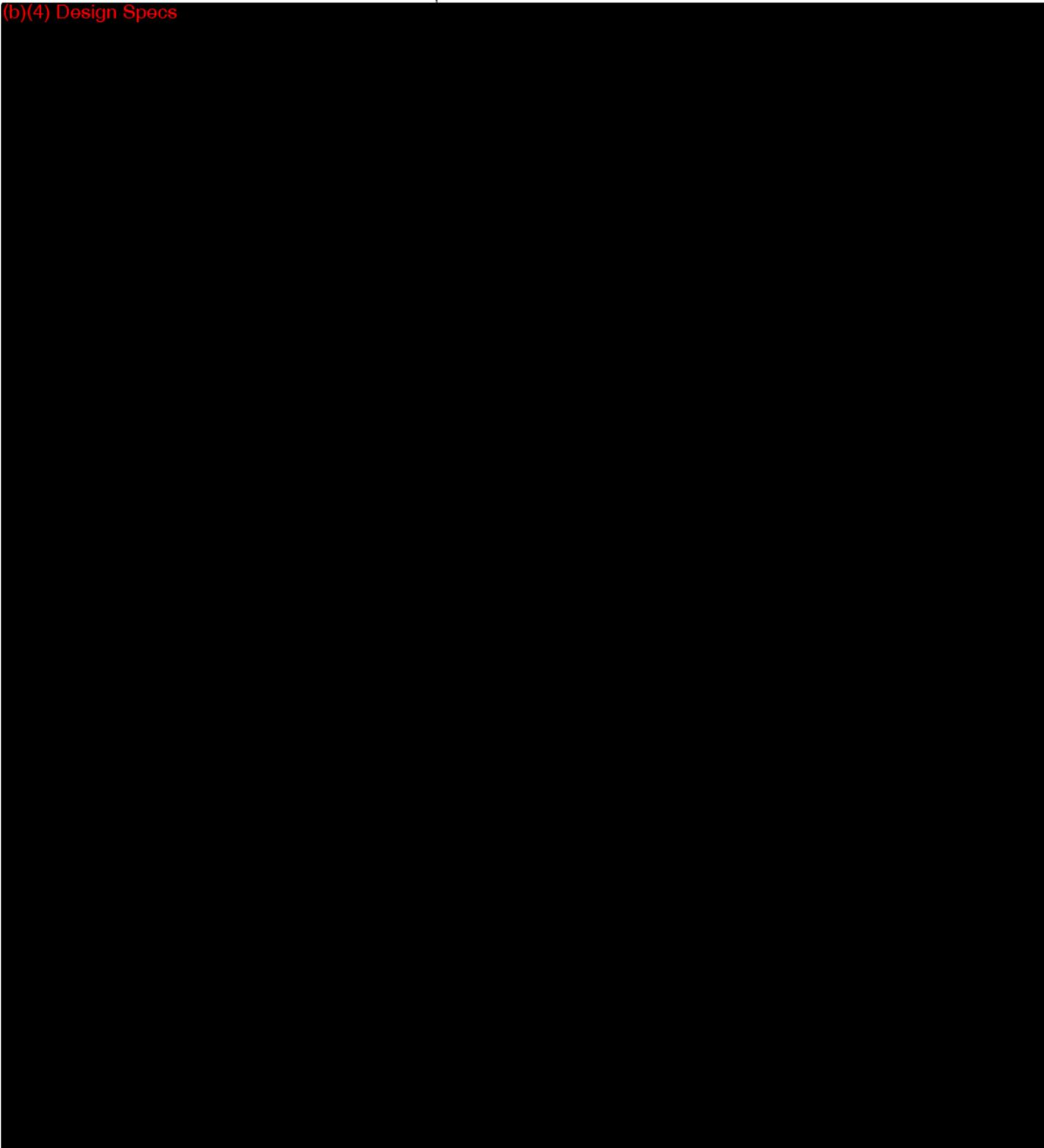
(b)(4) Product Specs



(b)(4) Design Specs



(b)(4) Design Specs



Attachment 2

Attachment 3

Attachment 4

Attachment 5

Attachment 6

Attachment 7

Attachment 8

Attachment 9

Attachment 10

Attachment 11

Attachment 12

