U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K992969 - 102 pages
COMPANY:	RESPIRONICS, INC. (RESPIRONICS)
PRODUCT:	VENTILATOR, NON-CONTINUOUS (RESPIRATOR) (BZD)
SUMMARY:	Product: RESPIRONICS TOTAL FACE MASK
DATE REQUESTED:	Sep 28, 2016
DATE PRINTED:	Sep 28, 2016
Note:	Printed

ATTACHMENT 4

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact	David J. Vanella Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Classification Reference	21 CFR 868.5905
Product Code	BZD – noncontinuous ventilator
Common/Usual Name	nasal mask
Proprietary Name	Respironics® Total™ Face Mask
Predicate Device	Total Face Mask (K925920)
Reason for submission	Modified design; modified materials.

Substantial Equivalence

The modified mask has the following similarities to the previously cleared predicate device:

- Same intended use.
- Same operating principle.
- Same technology.
- Same manufacturing process.

Design verification tests were performed on the Total Face Mask as a result of the risk analysis assessment, and acceptance criteria were met. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the mask described in this submission is substantially equivalent to the predicate device.

The modified mask complies with the applicable standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications," November 1993.

Device Description/Intended Use

The Total Face Mask is intended to provide a single-patient-use interface for adult patients (>30 kg) receiving Respironics CPAP or BiPAP therapy. The mask (Figure 1) fits over the entire face, with the rim of the mask framing the face along the hairline and jawline. The mask consists of a polycarbonate faceplate and a thin silicone cushion that folds inward, creating a flap on the inner perimeter of the mask to improve seal. The faceplate has four Velcro® hooks to which the headgear tabs attach.

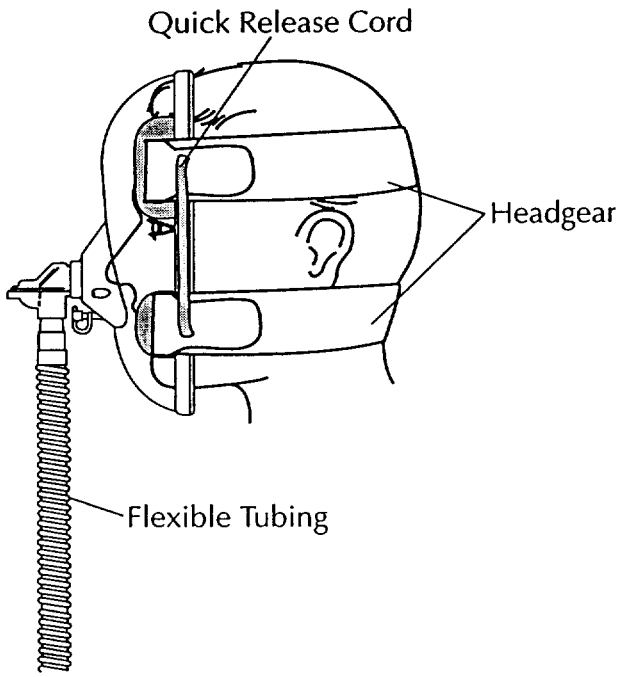

Figure 1. Respironics® Total™ Face Mask & headgear

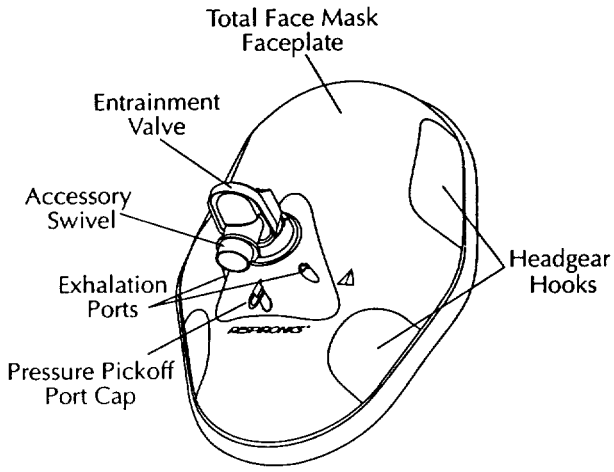

Figure 2. Respironics® Total™ Face Mask

The modified faceplate (Figure 2) is smaller, rounder, and has a streamlined profile. (Predicate mask is larger, primarily round, with the exception of the eye area, which is squared off.) Modified mask volume is smaller at 1550 ml. (Predicate volume is 2300 ml.) Modified mask cushion material is silicone. (Predicate cushion is urethane.)

Modified faceplate (Figure 2) has a nosepiece with 22-mm entrainment valve, whose accessory swivel connects to patient circuit. (Predicate faceplate has a 22-mm elbow, to which patient circuit is connected.) Entrainment valve opens to ambient air if pressure should cease. (Predicate requires use of a non-rebreathing valve (NRV).) Two built-in exhalation ports are located on the nosepiece. (Predicate's ports are located on the mask.) Nosepiece has one pressure pickoff port. (Predicate elbow has two.) The headgear consists of Velcro® straps. (Predicate headgear is a cap with Velcro straps.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

Mr. David J. Vanella
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550

Re: K992969
Total Face Mask
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: October 8, 1999
Received: October 12, 1999

Dear Mr. Vanella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James A Wentworth for,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992969

Device Name: Respironics® Total™ Face Mask

Intended Use/Indications for Use

The Respironics® Total™ Face Mask is intended to provide an interface for application of Respironics CPAP or BiPAP therapy to patients.

Environment of Use/Patient Population

For single patient use in the home or hospital/institutional environment. The mask is to be used on adult patients (>30 kg) for whom CPAP or BiPAP therapy has been prescribed using a Respironics CPAP or BiPAP system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992969

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

Mr. David J. Vanella
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550

Re: K992969
Total Face Mask
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: October 8, 1999
Received: October 12, 1999

Dear Mr. Vanella:

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Sincerely yours,

James A Wentworth for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992969

Device Name: Respironics® Total™ Face Mask

Intended Use/Indications for Use

The Respironics® Total™ Face Mask is intended to provide an interface for application of Respironics CPAP or BiPAP therapy to patients.

Environment of Use/Patient Population

For single patient use in the home or hospital/institutional environment. The mask is to be used on adult patients (>30 kg) for whom CPAP or BiPAP therapy has been prescribed using a Respironics CPAP or BiPAP system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992969

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) James Lee

Subject: 510(k) Number K992969/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices. EXN 11/8/99
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☐ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☒ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 73 BZD / II (TWO) /

Additional Product Code(s) with panel (optional):

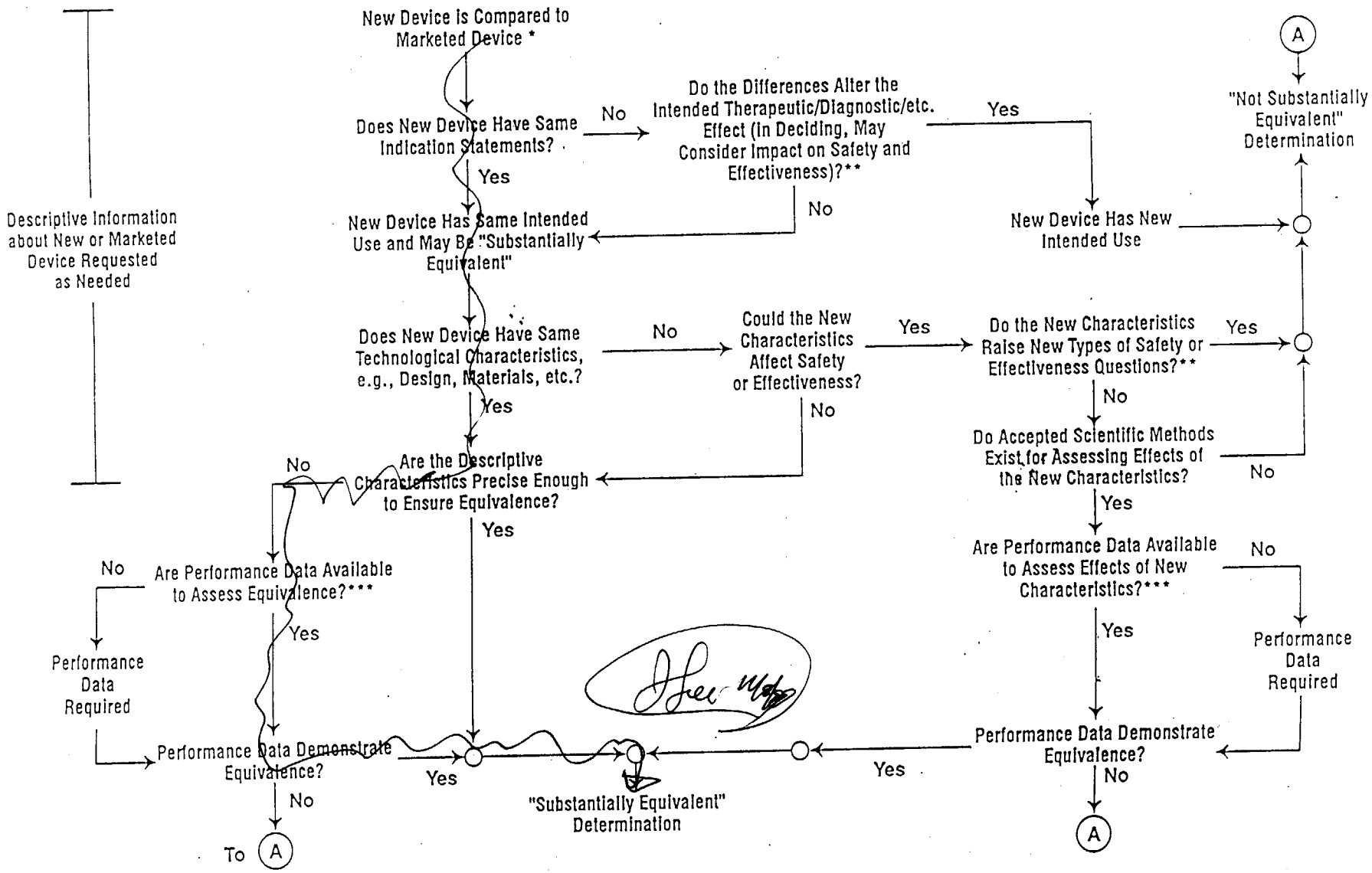
Review: [signature] (Branch Chief) ADDB (Branch Code) 11/8/99 (Date)

Final Review: [signature] (Division Director) 11.9.99 (Date)

Revised:8/17//99

4

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissi... ...mpare New Devices to Marketed Devices. FDA Requests Additional Infor... the Relationship Between Marketed and "Predicate" (Pre-Amendmen... ...classified Post-Amendments) Devices Is Unclear.

** This Decis... Normally Based on Descriptive Information Alone, But Limited T... formation Is Sometimes Required.

*** Data May ... ...e 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K992969

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Reserved Class I device. The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

   (Yes, the information is in the original submittal.)

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.

   (Yes, the subject device has the identical indication for use statement with repect to the predicate device.)

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   (The company submitted the information to address this item. This includes the justification, test reports, etc.)

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics.

   (The information is located in the original submittal.)

5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified In 21 CFR 820.30 and the records are available for review.

   (Yes, the company submitted the information in Attachment 3 to address this item.)

6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**
   (Yes, the information is in the file.)

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

Lee 11/8/99

(Reviewer's Signature) (Date)

Comments This file was re-assigned to me on 10/18/99, It is a modification of a marked device, (K 925920). The Prod. Code has been updated in this file.

revised:3/27/98

EXW 11/8/99

The file was originally refused to accept.

Respironics, Inc. *1001 Murry Ridge Lane • Murrysville, Pennsylvania 15668-8550*

Date: November 8, 1999

To: Emil Wang
Fax: (301) 480 - 4204

From:
Fax: **724/387-4223**

Number of pages including cover sheet: 2

Dear Mr. Wang:

Attached is the correspondence / Information you require to complete your review.

Thank-You

RESPIRONICS®

1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA
Telephone: 1-724-733-0200
Fax: 1-724-387-5299

November 8, 1999

Emil Wang
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
900 Corporate Blvd.
Rockville, MD 20850

RE: Respironics Total Face K992969

Dear Mr. Wang:

Pursuant to our conversation today, November 8, 1999 regarding the labeling for the Total Face Mask we have agreed to include the following information into the product labeling. *"The deadspace volume of the mask is 1500 cc. The volume of the area around the noice piece and entrainment valve where most of the gas exchange occurs is 80 cc."*

If you require additional information please feel free to contact me at (724) 733-5866 or Elias Diacopoulos at (724) 733-5807. My fax number is (724) 387-4206. Thank you for your prompt review.

Sincerely,

David J. Vanella
Manager, Regulatory / Clinical Affairs

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 13, 1999

RESPIRONICS, INC.
1001 MURRY RIDGE DR.
MURRYSVILLE, PA 15668
ATTN: DAVID J. VANELLA

510(k) Number: K992969
Product: RESPIRONICS
TOTAL FACE MASK

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 (HFZ-401) 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. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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 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.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

CDRH SUBMISSION COVER SHEET

Date of Submission: 8 October 1999	FDA Document Number: K992969/S1

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☐ Original submission: ☐ Traditional ☐ Special ☐ Abbreviated ☒ Additional information: ☐ Traditional ☒ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B — Applicant or Sponsor

Company / Institution name: Respironics Inc.	Establishment registration number: 2518422
Division name (if applicable): Homecare Division	Phone number (include area code): (724) 733-5866
Street address: 1001 Murry Ridge Lane	FAX number (include area code): (724) 387-4206

City:	State / Province:	Country:
Murrysville	PA 15668	USA

Contact name: David J. Vanella	
Contact title: Manager, Regulatory Affairs	Contact e-mail address: David.vanella@respironics.com

Section C — Submission correspondent (if different from above)

Company / Institution name:	Establishment registration number:
Division name (if applicable):	Phone number (include area code): ( )
Street address:	FAX number (include area code): ( )

City:	State / Province:	Country:

Contact name:	
Contact title:	Contact e-mail address:

Section D1 — Reason for Submission — PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement

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

- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site

- ☐ Other reason (specify):

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

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)

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

- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment

- ☐ Change in ownership
- ☐ Change in correspondent

Section D2 — Reason for Submission — IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request

- ☐ Other reason (specify):

- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final

- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting

Section D3 — Reason for Submission — 510(k)

- ☐ New device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):

- ☐ Change in technology
- ☒ Change in design

- ☒ Change in materials
- ☐ Change in manufacturing process

Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 73BZD	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
- [x] 510(k) summary attached
- [ ] 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K925920	1 Total Face Mask	1 Respironics Inc.
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F — Product Information — Applicable to All Applications

Common or usual name or classification name:

Nasal Mask

Trade or proprietary or model name	Model number
1 Respironics® Total™ Face Mask	1
2	2
3	3
4	4
5	5

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

1 K925920	2 K961915	3 K991648	4	5	6
7	8	9	10	11	12

Data included in submission: [ ] Laboratory testing [ ] Animal trials [ ] Human trials

Section G — Product Classification — Applicable to All Applications

Product code: BZD

C.F.R. Section: 868.5905

Classification panel: Anesthesiology

Device class:
- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications (from labeling):

The Respironics® Total™ Face Mask is intended to provide an interface for application of Respironics CPAP or BiPAP therapy to patients. For single-patient-use in the home or hospital/institutional environment on adult patients (>30 kg) for whom CPAP or BiPAP therapy has been prescribed using a Respironics CPAP or BiPAP system.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 2518422	☒ Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☐ Repackager / relabeler
Company / Institution name: Respironics Inc.		Establishment registration number: 2518422
Division name (if applicable): Regulatory Affairs		Phone number (include area code): (724) 733-5866
Street address: 1001 Murry Ridge Lane		FAX number (include area code): (724) 387-4206
City: Murrysville	State / Province: PA 15668	Country: USA
Contact name: David J. Vanella		
Contact title: Manager, Regulatory Affairs		Contact e-mail address: David.Vanella@respironics.com

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code): ( )
Street address:		FAX number (include area code): ( )
City:	State / Province:	Country:
Contact name:		
Contact title:		Contact e-mail address:

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract sterilizer ☐ Contract manufacturer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code): ( )
Street address:		FAX number (include area code): ( )
City:	State / Province:	Country:
Contact name:		
Contact title:		Contact e-mail address:

RESPIRONICS®

1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA
Telephone: 1-724-733-0200
Fax: 1-724-387-5299

8 October 1999

ATTN: Joanna Weitershausen
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: Total Face Mask Special 510(k) K992969

Dear Ms. Weitershausen:

Respironics is responding to your September 14, 1999 request for more information.

(b)(4)Proprietary Information

[redacted]

15

(b)(4)Proprietary Information

[redacted]

We hope this information enables you to complete your review of the submission. Thank you.

Sincerely,

David J. Vanella
Manager, Regulatory Affairs

Attachment 1

"Design Verification Test Procedure and Report for the Total Facemask"

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

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(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

(b)(4)Proprietary Information-Testing

Attachment 2

User Instructions and Test Results

DRAFT

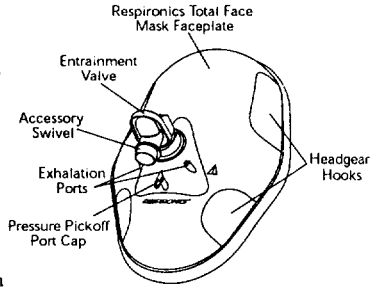
Respironics® Total™ Face Mask

Instructions for Use

Reorder #302433

LATEX-FREE

Single Patient Use Only



The Respironics Total Face Mask is intended to provide an interface for adult patients when used with Respironics CPAP or BiPAP® therapy. The mask contains exhalation ports that provide a continuous leak path in the patient circuit. This mask does not require the use of a separate exhalation device; however, you can use it with additional Respironics exhalation devices if you remove the accessory swivel.

Warnings

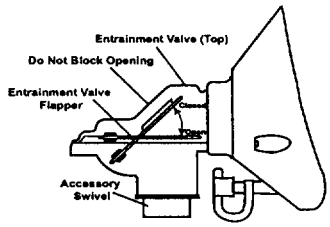
- The Respironics Total Face Mask is designed for use with CPAP and BiPAP systems recommended by your physician or respiratory therapist. Do not wear this mask unless the CPAP or BiPAP system is turned on and operating properly. Do not try to block or seal the exhalation ports in the mask.

  Most CPAP systems have the potential to allow rebreathing of exhaled air. CPAP systems are designed for use with masks (or connectors) that have vent holes or exhalation ports. When the CPAP system is turned on, new air from the system flushes the exhaled air out through the vent holes. If the CPAP system is not operating, the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.
- A minimum pressure of 5 cm H_2O must be maintained when using the Respironics Total Face Mask.
- System pressure and oxygen therapy may be different for a Respironics Total Face Mask than for a nasal or nasal/oral interface. When changing mask types, determine the appropriate pressure level and oxygen therapy. Because a small leak exists at the nose area of the mask and through the exhalation ports, you must ensure that the pressure and oxygen therapy are maintained against this higher leak level.
- When including an additional exhalation device to the patient circuit, you may need to adjust the pressure level to compensate for the additional leak of the exhalation device.
- The entrainment valve contains a magnet. Do not use this mask in or near magnetic resonance imaging (MRI) equipment.
- To minimize the risks of vomiting during sleep, the patient should avoid eating or drinking for three hours before use.
- The patient's physician should be contacted if the patient experiences the following symptoms while using the mask or after removing it: Unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision (consult an opthamologist if symptoms persist).

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

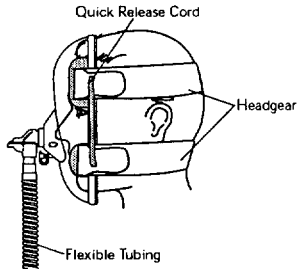
Contraindications

This mask may not be suitable for use on patients with the following conditions: glaucoma, recent eye surgery or dry eyes, nocturnal vomiting, hiatal hernia, impaired cardiac sphincter function, or patients unable to remove the mask.



Verifying Entrainment Valve Function

With the unit turned off, the entrainment valve flapper (internal blue disk) should be open, allowing the user to breathe room air. Turn the unit On. The flapper should close, allowing the user to receive air flow from the unit. If the valve does not function in this manner, disassemble it, make sure the flapper is properly aligned, and reassemble. If the valve still does not function properly, notify your home care dealer. Do not block the opening on the entrainment valve. Check the valve before each use for dysfunction or any blockage by patient secretions. To ensure proper entrainment valve function, verify that the flapper is free moving and dry.

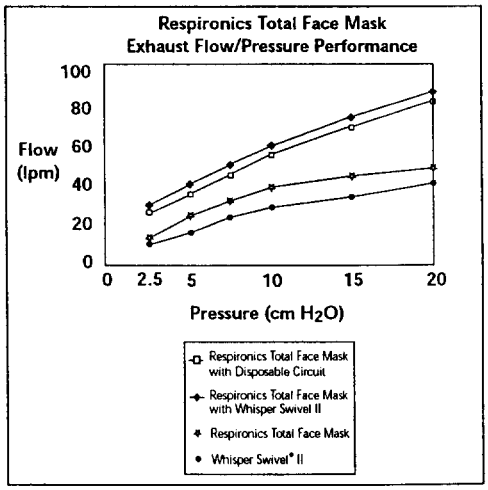


Connecting the Mask and Headgear

1. Set up the CPAP or BiPAP unit and patient circuit according to the unit's instruction manual.
2. To ensure a proper fit, place the patient's chin in the mask first, then lightly press the mask against the patient's face.
3. Pull the headgear straps around each side of the head and secure them to the mask. Do not overtighten the straps. Overtightening can cause or worsen leaks.
4. Connect the circuit tubing to the mask swivel. Turn the CPAP or BiPAP unit on.
5. Verify that there is only minor lifting of the mask from the patient's face (approximately 1/4" to 1/2") during a full respiratory cycle. Have the patient assume various sleeping positions (e.g., supine, lateral, prone) with the mask in place. Readjust the straps if necessary. If the inner flap covers the mouth, readjust the mask fit.

Removing the Mask and Headgear

To remove the mask quickly, pull on the quick release cord, away from the patient's face, and remove the mask. The mask and headgear can also be removed by detaching the headgear straps from the tabs on the mask.



Cleaning and Storage

Clean all parts of the mask daily. Clean the headgear at least once each week or more often if needed. Before cleaning, disconnect the mask and headgear.

Mask

Do not use alcohol, cleaning solutions containing alcohol, or any strong household cleaners.

1. Hand wash the mask in warm water with a mild dishwashing detergent. Do not use cleaners containing moisturizers. Do not use bleach.
2. Rinse thoroughly. Air dry. Make sure the mask is dry before use. Replace the mask if any parts are damaged.

Headgear

1. Hand or machine wash with a standard laundry detergent and warm water. Rinse thoroughly. Do not use bleach.
2. Line dry or machine dry at the medium heat setting.

The mask should last approximately one year when cleaned according to these instructions.

Helpful Tips for Mask Comfort

- Clean the mask thoroughly before every use, including first-time usage.
- Clean the patient's face thoroughly before each use.
- Make sure the mask and headgear are the correct size for the patient's face. If excessive discomfort is experienced, have the mask readjusted or consider an alternative mask.
- Do not overtighten the headgear. Overtightening can irritate the patient's face, increase leaks, or cause damage to the cushion.

RESPIRONICS INC.®
1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA

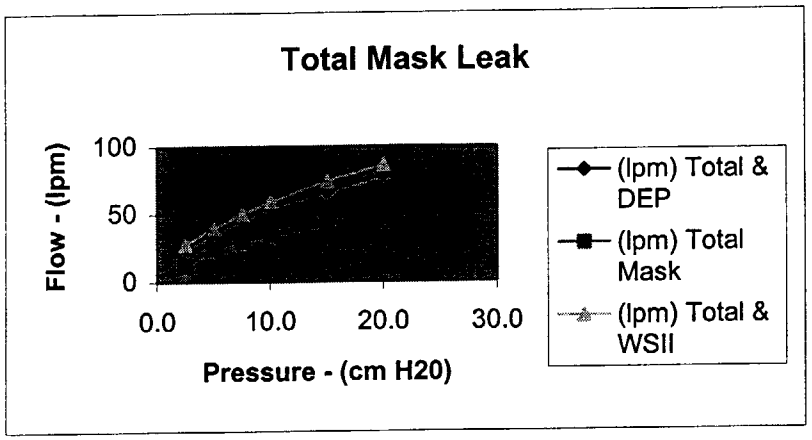
RESPIRONICS®
Deutschland
Gewerbestrasse 17
82211 Herrsching Germany

CE 0123

1002964
JBM 10/6/99

This information appears on the User Instructions.

(cm h20) Pressure	(lpm) Total & DEP	(lpm) Total Mask	(lpm) Total & WSII
2.5	25	12	28
5.0	37	25	40
7.5	46	30	50
10.0	55	35	59
15.0	67	42	74
20.0	79	48	86



Attachment 3

Special 510(k)

SPECIAL 510(k)

TOTAL FACE MASK

Date of Submission	6 October 1999
Device Trade Name	Respironics® Total™ Face Mask
Common/Usual Name	Face Mask
Establishment Registration #	2518422
Address of Mfr. Facility	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 724/733-5866 FAX: 724/387-4206
Classification	Class II device
Classification Panel	Anesthesiology Devices
Classification Reference	21 CFR 868.5905
Product Code	BZD
Predicate Device	Respironics Total Face Mask (K925920)
Labeling	Draft Labeling can be found in Attachment 1.
Intended Use	The Total Face Mask is intended to provide a single-patient-use interface for adult patients (>30 kg) receiving Respironics CPAP or BiPAP therapy. This is the **same intended use** as previously cleared for the Total Face Mask. Please see the Indications for Use Statement in Attachment 2.
Device Description	The Total Face Mask (Figure 1) consists of a polycarbonate faceplate and a thin silicone cushion that folds inward, creating a flap on the inner perimeter of the mask to improve seal. The nosepiece, the area to which the patient tubing circuit connects, has two integral exhalation ports, an entrainment valve, and a pressure pickoff port. The Total Face Mask fits over the entire face, with the rim of the mask framing the face along the hairline and jawline. The faceplate has four Velcro® hooks to which the headgear tabs attach.

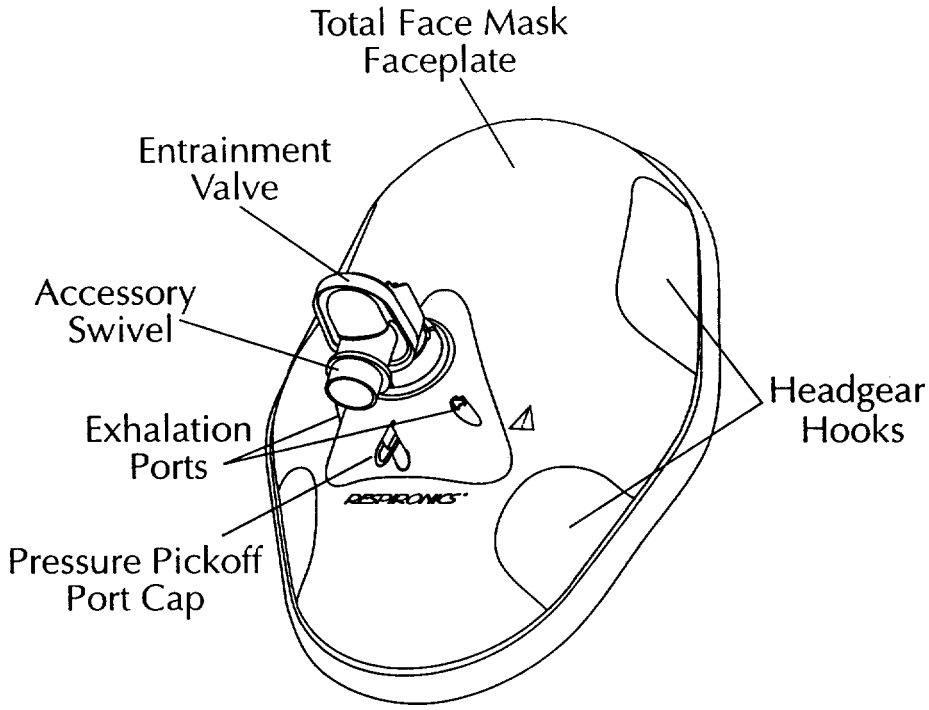


Figure 1. Respironics® Total™ Face Mask.

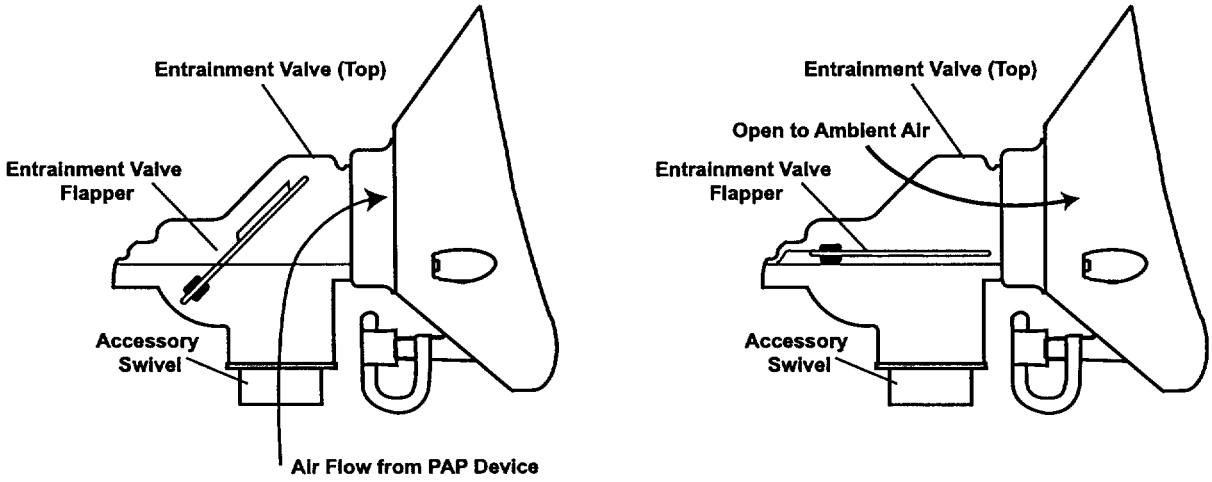


Figure 2. Total Face Mask Nosepiece (including entrainment valve).

AT LEFT: When PAP device is on, valve flapper closes to atmosphere so air flow from device reaches the patient.

AT RIGHT: If device pressure should cease, valve flapper opens to atmosphere so patient has fresh air inlet.

Purpose of the Modification

The purpose of the design modification is to **decrease mask volume.**

The faceplate is smaller, rounder, and has a streamlined profile.

Other minor modifications (discussed in the following comparison section) have been made to improve the design.

There have been no changes in:

- ❑ Intended use
- ❑ Operating principle
- ❑ Technology
- ❑ Manufacturing process

Respironics has determined that the modifications, as specified within, have no impact on the safety and effectiveness of the device.

Device Comparison

Modifications made to the faceplate and cushion (Figure 1):

- ❑ The modified faceplate is smaller, rounder, and has a streamlined profile. (Predicate mask is larger, primarily round, with the exception of the eye area, which is squared off.)
- ❑ Modified mask volume is 1550 ml. (Predicate volume is 2300 ml.)
- ❑ Modified mask cushion material is silicone. (Predicate cushion is urethane.) Silicone is used on many other masks, including the reusable nasal mask (K991648).

Modifications made to the patient circuit connection (Figures 1, 2 and 3):

- ❑ Modified faceplate has a nosepiece with 22-mm entrainment valve, whose accessory swivel connects to patient circuit. (Predicate faceplate has a 22-mm elbow, to which patient circuit is connected.)
- ❑ *Entrainment valve operating characteristics are unchanged*: When PAP device is on (i.e., airway pressure $\geq$1 and $\leq$3 cm H_2O), valve flapper closes to atmosphere, so that air flow from device reaches the patient. (Valve remains closed to atmosphere at all positive airway pressures $\geq$1 cm H_2O). If device pressure should cease (i.e., pressure $\geq$-1 and $\leq$ 1 cm H_2O), valve flapper opens to atmosphere, so the patient has a fresh air inlet.

  Valve was cleared with the Respironics Spectrum Full Face Mask (K961915). (Predicate requires use of a non-rebreathing valve (NRV).)

Device Comparison (CONTINUED)

Patient circuit connection (CONTINUED)

- Two built-in exhalation ports are located on the nosepiece. (Predicate's two built-in ports are located on the mask.)
- Nosepiece has one pressure pickoff port. (Predicate elbow has two. Historically, the second pickoff port was not being used.)

Modifications made to the headgear (Figure 3):

- The headgear consists of Velcro® straps. (The predicate headgear was a cap with Velcro® straps.)

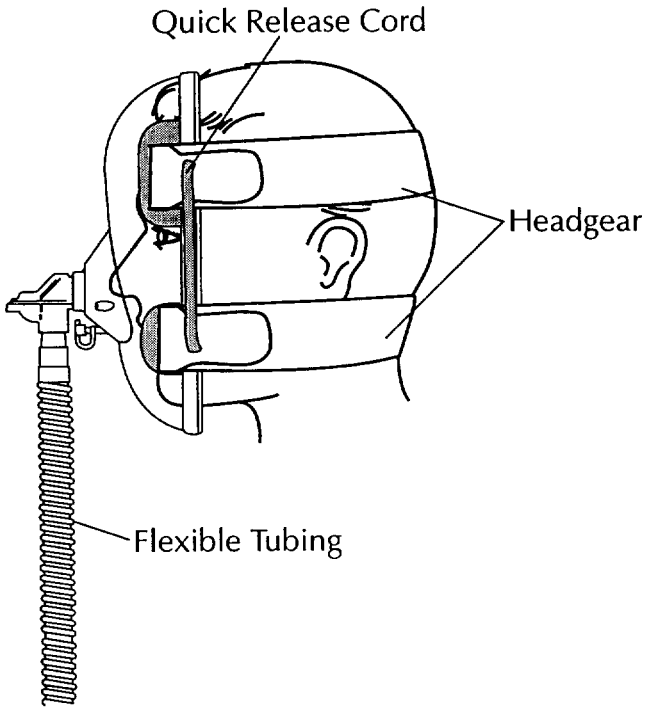


Figure 3. Respironics® Total™ Face Mask with headgear.

Substantial Equivalence

The modified mask has the following similarities to the previously cleared predicate device:

- Same intended use.
- Same operating principle.
- Same technology.
- Same manufacturing process.

In summary, the mask described in this submission is substantially equivalent to the predicate device.

Table 1 – Comparison of Devices

	Total Face Mask (K925920)	**Total Face Mask (Modified Device)**
Intended Use	Same.	
Operating Principle	Same.	
Patient Population	Same.	
Technology	Same.	
Manufacturing Process	Same.	
Provided Non-sterile	Same.	
Single Patient Use, Reusable	Same.	
Faceplate Material	Same.	
Cushion Design	Same.	
Shape and size of Faceplate	Larger, primarily round, with the exception of the eye area, which is squared off to allow a clearer field of vision.	Smaller, rounder, streamlined profile.
Exhalation Device	Exhalation ports on mask. Non-rebreathing valve (NRV) required for use.	Exhalation ports on nosepiece. Optional use of additional Respironics exhalation devices. Entrainment valve opens to ambient air if pressure should cease.
Number of Pressure Pickoff Ports	Two.	One.
Cushion Material	Urethane.	Silicone.
Mask Volume	2300 ml.	1550 ml.
Patient Circuit Connection	22-mm elbow. NRV has swivel that connects to 6-ft patient circuit.	22-mm entrainment valve. Valve has accessory swivel that connects to 6-ft. patient circuit.
Headgear	Cap with Velcro® straps.	Velcro® straps.

Continued on next page.

Summary of Design Control Activities	❑ The risk analysis method used to assess the impact of the re-design was a hazards analysis, consisting of identification of qualitative and quantitative characteristics related to the mask, identification of possible hazards, estimation of the risks for each hazard, determination of acceptability of risk, and risk reduction. ❑ The design verification tests that were performed as a result of this risk analysis assessment are listed in Table 2 **(on next page).** ❑ Test methods are the same as those used in the original 510(k) submission. ❑ A declaration of conformity with design controls is in Attachment 3.
510(k) Summary	A 510(k) Summary of Safety & Effectiveness is included in Attachment 4.
Truthful & Accuracy	A certification of the truthfulness and accuracy of the Total Face Mask described in this submission is provided in Attachment 5.

Please turn the page for "Table 2 – Verification Test Summary."

Table 2 – Verification Test Summary

(b)(4)Proprietary Information-Testing

[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1999

Mr. David J. Vanella
Manager, Regulatory Affairs
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550

Re: K992969
Total Face Mask
Dated: September 2, 1999
Received: September 3, 1999

Dear Mr. Vanella:

We have completed an administrative review of your section 510(k) Premarket Notification (510(k)) of intent to market the device referenced above. Our review indicates that your 510(k) is administratively incomplete and we are placing your 510(k) on hold. We believe that this basic information is necessary for us to begin our substantive review and to determine whether or not this device is substantially equivalent to devices marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (Act). Therefore, in order for us to begin the substantive review of your 510(k) submission we require the following:

(b)(4)Proprietary Information

[redacted]

59

(b)(4)Proprietary Information

[redacted]

The additional information should be submitted in duplicate, referencing the 510(k) number above to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Please note that since your 510(K) submission has not been substantively reviewed, additional information may be required during the review process and the file may again be placed on hold. You may not market this device until you have provided adequate information as required by 21 CFR 807.87 and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations (21 CFR part 812).

If the requested information is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days, it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. If you have any questions concerning the contents of this letter, please contact Joanna Weitershausen at (301) 443-8609 Ext-164. If you have procedural or policy questions, please contact the Division of

Small Manufacturers Assistance at (301) 443-6597 or its toll free number (800) 638-2041, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Mr. David J. Vanella
Manager, Regulatory Affairs
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550

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(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

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Food and Drug Administration
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Rockville, Maryland 20850

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Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Prepared by:JWeitershausen:att/9/14/99
Final:att/9/14/99

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ 480	JWeitershausen	9.14.99						

U.S. GPO 1986-169-089

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s)_____

Subject: 510(k) Number 992969

To: The Record - It is my recommendation that the subject 510(k) Notification:

☐ Refused to accept.
☐ Requires additional information (other than refuse to accept).
☐ Is substantially equivalent to marketed devices.
☐ NOT substantially equivalent to marketed devices.
De Novo Classification Candidate? ☐ YES ☐ NO
☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☐ NO
Is this device subject to the Tracking Regulation?	☐ YES	☐ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☐ NO
Is this a prescription device?	☐ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☐ NO
Special 510(k)?	☐ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☐ NO

This 510(k) contains:
Truthful and Accurate Statement ☐ Requested ☐ Enclosed
(required for originals received 3-14-95 and after)
☐ A 510(k) summary OR ☐ A 510(k) statement
☐ The required certification and summary for class III devices
☐ The indication for use form (required for originals received 1-1-96 and after)
Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):
☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

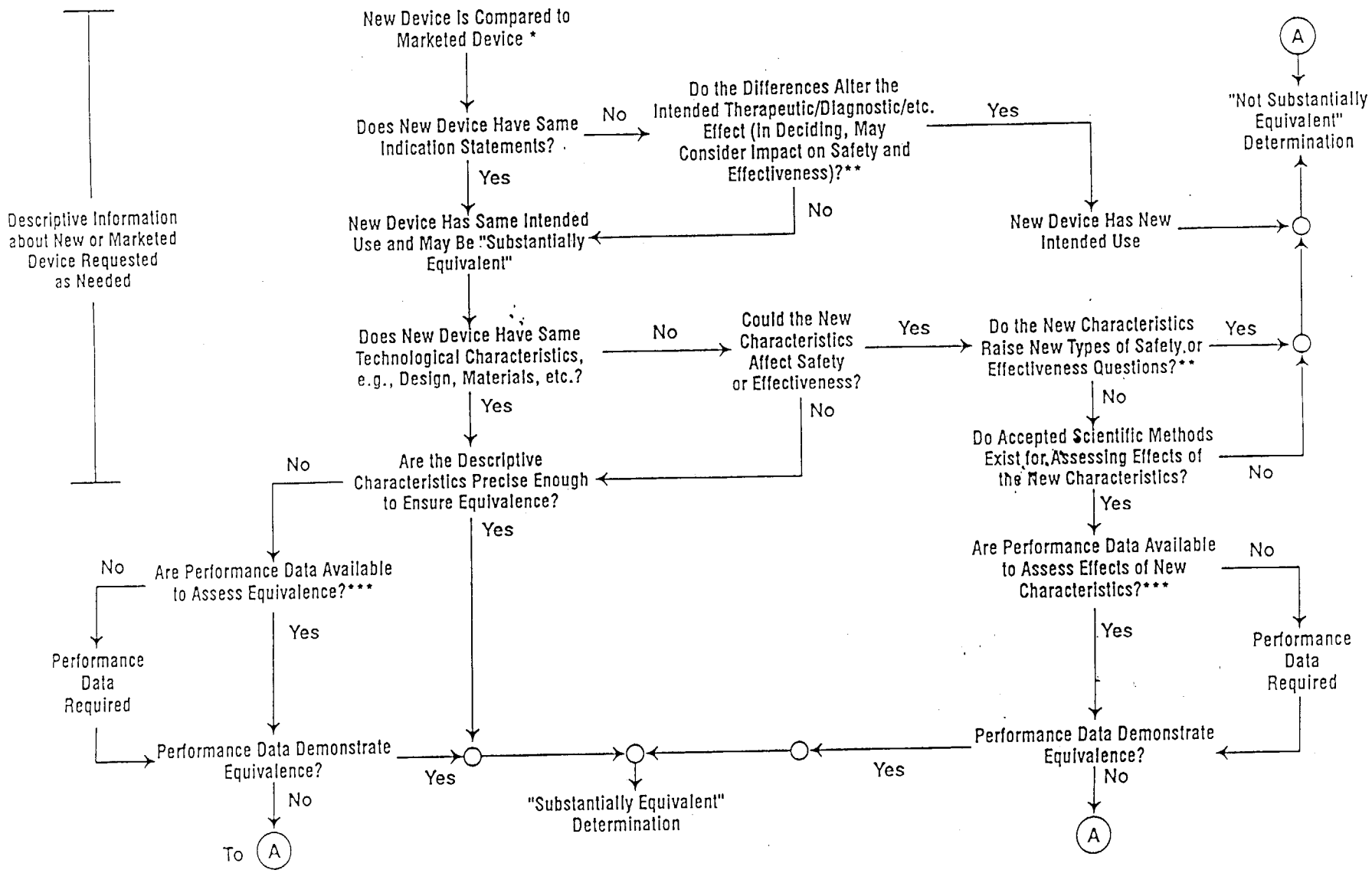
_____ _____

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Revised:8/17//99

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) ... issions Compare New Devices to Marketed Devices. FDA Requests Addi... ormation If the Relationship Between Marketed and "Predicate" (Pre-A... ients or Reclassified Post-Amendments) Devices Is Unclear.

** This De... is Normally Based on Descriptive Information Alone, But Limite... Information Is Sometimes Required.

*** Data M... the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: Total Face Mask | K992969

Submitter (Company): Respironics, Inc.

Items which should be included (circle missing & needed information)	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2 4,5		
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	NA		YES		NO		
	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class	✓						
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA						
d) compliance with Section 514 - performance standards	NA						
e) address of manufacturer	✓						
f) Truthful and Accurate Statement							
g) Indications for Use enclosure	✓						
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*							
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals	✓						
k) Proposed Labeling:	✓						
i) package labeling (user info)	✓						
ii) statement of intended use	✓						
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:	✓						
i) Labeling							✓
ii) intended use	✓						
iii) physical characteristics	✓						
iv) anatomical sites of use	assumed						
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification							
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR*			* If no - STOP not a special				

*USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED**				
c) *STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED**	✓		* If no - STOP not a special	
d) Design Control Activities Summary	✓			
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis	✓			
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied	✓			
iii) A declaration of conformity with design controls. The declaration of conformity should include:	✓			
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met	✓			
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.	✓			

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

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inapplicable requirements or deviations noted below					
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed					
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device					
v) A specification of any deviations from each applicable standard that were applied					
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference					
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations					
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards					

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							✓
i) component & material							✓
ii) identify patient-contacting materials							✓
iii) biocompatibility of final sterilized product							✓
b) Sterilization and expiration dating information:	N/A						
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:	N/A						
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No**

Date: 9/13/99

Reviewer: Jerry L. Smallwood

Concurrence by Review Branch: ____

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

	YES	NO	
1. Is Product A Device			If **NO** = Stop
2. Is Device Subject To 510(k)?			If **NO** = Stop
3. Same Indication Statement?			If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5. Same Technological Characteristics?			If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10. Performance Data Available?			If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 03, 1999

RESPIRONICS, INC.
1001 MURRY RIDGE DR.
MURRYSVILLE, PA 15668
ATTN: DAVID J. VANELLA

510(k) Number: K992969
Received: 03-SEP-1999
Product: RESPIRONICS TOTAL FACE MASK

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

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

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992969

RESPIRONICS®

1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA
Telephone: 1-724-733-0200
Fax: 1-724-387-5299

2 September 1999

ATTN: Document Control Clerk
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ - 401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA/CDRH/ODE/DMC
3 SEP 99 10 23
RECEIVED

RE: K925920
Total Face Mask (declared SE on 7/21/93)

Dear Document Control Clerk:

Respironics Inc. hereby submits this **Special 510(k): Device Modification** for our Total Face Mask. Respironics has reduced the size and modified the shape of the mask faceplate. Other minor modifications have been made to improve the design, and are discussed within. We believe that these modifications are eligible for the Special 510(k), because the fundamental scientific technology and intended use are unchanged.

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

Thank you in advance for your consideration of our application. If you require additional information, please do not hesitate to contact me by phone at (724) 733-5866, or at the address shown above.

Sincerely,

David J. Vanella
Manager, Regulatory Affairs

AN II

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CDRH SUBMISSION COVER SHEET

Date of Submission: September 2, 1999	FDA Document Number:

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☒ Original submission: ☐ Traditional ☒ Special ☐ Abbreviated ☐ Additional information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B — Applicant or Sponsor

Company / Institution name: Respironics Inc.	Establishment registration number: 2518422
Division name (if applicable): Sleep Business Unit	Phone number (include area code): (724) 733-5866
Street address: 1001 Murry Ridge Lane	FAX number (include area code): (724) 387-4206
City: Murrysville / State / Province: PA 15668	Country: USA
Contact name: David J. Vanella	
Contact title: Manager, Regulatory Affairs	Contact e-mail address: David.vanella@respironics.com

Section C — Submission correspondent (if different from above)

Company / Institution name:	Establishment registration number:
Division name (if applicable):	Phone number (include area code): ( )
Street address:	FAX number (include area code): ( )
City: / State / Province:	Country:
Contact name:	
Contact title:	Contact e-mail address:

Section D1 — Reason for Submission — PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Process change
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf life
  - ☐ Trade name
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
  - ☐ Device defect
  - ☐ Amendment
- ☐ Change in ownership
- ☐ Change in correspondent

Section D2 — Reason for Submission — IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting

Section D3 — Reason for Submission — 510(k)

- ☐ New device
- ☒ Additional or expanded indications
- ☐ Other reason (specify):
- ☐ Change in technology
- ☒ Change in design
- ☒ Change in materials
- ☐ Change in manufacturing process

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 data:
1 73 BZD	2	3	4	☒ 510(k) summary attached
5	6	7	8	☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K925920	1 Total Face Mask	1 Respironics Inc.
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F — Product Information — Applicable to All Applications

Common or usual name or classification name:

Nasal Mask

Trade or proprietary or model name	Model number
1 Respironics® Total™ Face Mask	1
2	2
3	3
4	4
5	5

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

1 K925920	2 K961915	3 K991648	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Section G — Product Classification — Applicable to All Applications

Product code: BZD	C.F.R. Section: 868.5905	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Anesthesiology		

Indications (from labeling):

The Respironics® Total™ Face Mask is intended to provide an interface for application of Respironics CPAP or BiPAP therapy to patients. For single-patient-use in the home or hospital/institutional environment on adult patients (>30 kg) for whom CPAP or BiPAP therapy has been prescribed using a Respironics CPAP or BiPAP system.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 2518422	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: Respironics Inc.		Establishment registration number: 2518422	
Division name (if applicable): Regulatory Affairs		Phone number (include area code): (724) 733-5866	
Street address: 1001 Murry Ridge Lane		FAX number (include area code): (724) 387-4206	
City: Murrysville	State / Province: PA 15668	Country: USA	
Contact name: David J. Vanella			
Contact title: Manager, Regulatory Affairs		Contact e-mail address: David.Vanella@respironics.com	
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	

TABLE OF CONTENTS

RESPIRONICS® TOTAL™ FACE MASK

Front Matter

Cover Letter
CDRH Submission Cover Sheet

Special 510(k)

Device Name
Address and Registration Number
Device Class
Predicate Device Information
Labeling and Intended Use
Device Description and Comparison
Substantial Equivalence
Summary of Design Control Activities
510(k) Summary of Safety & Effectiveness
Truthful & Accuracy Certification

Attachment 1 - Draft Labeling

Attachment 2 - Indications for Use Statement

Attachment 3 - Declaration of Conformity with Design Controls

Attachment 4 - 510(k) Summary of Safety & Effectiveness

Attachment 5 - Certification of Truthfulness and Accuracy

(End of Section.)

SPECIAL 510(k)

TOTAL FACE MASK

Date of Submission	2 September 1999
Device Trade Name	Respironics® Total™ Face Mask
Common/Usual Name	Face Mask
Establishment Registration #	2518422
Address of Mfr. Facility	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 724/733-5866 FAX: 724/387-4206
Classification	Class II device
Classification Panel	Anesthesiology Devices
Classification Reference	21 CFR 868.5905
Product Code	BZD
Predicate Device	Respironics Total Face Mask (K925920)
Labeling	Draft Labeling can be found in Attachment 1.
Intended Use	The Total Face Mask is intended to provide a single-patient-use interface for adult patients (>30 kg) receiving Respironics CPAP or BiPAP therapy. This is the **same intended use** as previously cleared for the Total Face Mask. Please see the Indications for Use Statement in Attachment 2.
Device Description	The Total Face Mask (Figure 1) consists of a polycarbonate faceplate and a thin silicone cushion that folds inward, creating a flap on the inner perimeter of the mask to improve seal. The nosepiece, the area to which the patient tubing circuit connects, has two integral exhalation ports, an entrainment valve, and a pressure pickoff port. The Total Face Mask fits over the entire face, with the rim of the mask framing the face along the hairline and jawline. The faceplate has four Velcro® hooks to which the headgear tabs attach.

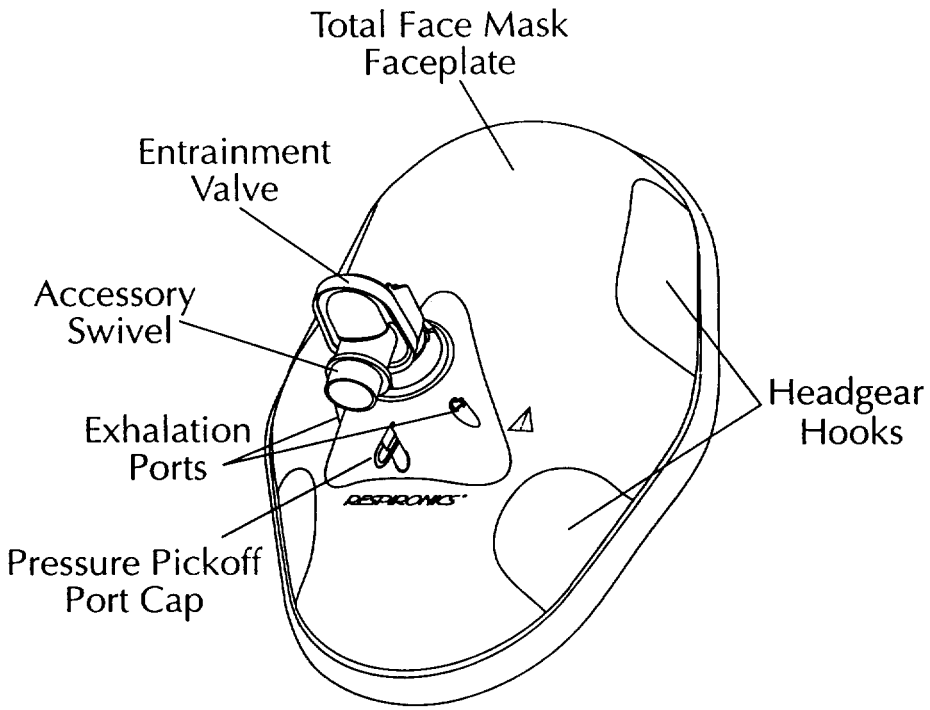

Figure 1. Respironics® Total™ Face Mask.

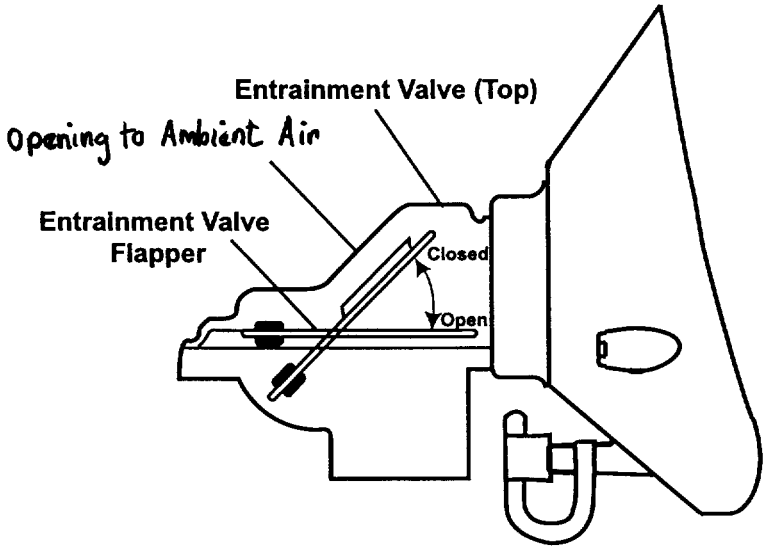

Figure 2. Respironics® Total™ Face Mask: Nosepiece.

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Purpose of the Modification

The purpose of the design modification is to **decrease mask volume.**

The faceplate is smaller, rounder, and has a streamlined profile.

Other minor modifications (discussed in the following comparison section) have been made to improve the design.

There have been no changes in:

- ❑ Intended use
- ❑ Operating principle
- ❑ Technology
- ❑ Manufacturing process

Respironics has determined that the modifications, as specified within, have no impact on the safety and effectiveness of the device.

Device Comparison

Modifications made to the faceplate and cushion (Figure 1):

- ❑ The modified faceplate is smaller, rounder, and has a streamlined profile. (Predicate mask is larger, primarily round, with the exception of the eye area, which is squared off.)
- ❑ Modified mask volume is 1550 ml. (Predicate volume is 2300 ml.)
- ❑ Modified mask cushion material is silicone. (Predicate cushion is urethane.) Silicone is used on many other masks, including the reusable nasal mask (K991648).

Modifications made to the patient circuit connection (Figures 1, 2 and 3):

- ❑ Modified faceplate has a nosepiece with 22-mm entrainment valve, whose accessory swivel connects to patient circuit. (Predicate faceplate has a 22-mm elbow, to which patient circuit is connected.)
- ❑ Entrainment valve opens to ambient air if pressure should cease. Valve was cleared with the Respironics Spectrum Full Face Mask (K961915). (Predicate requires use of a non-rebreathing valve (NRV).)
- ❑ Two built-in exhalation ports are located on the nosepiece. (Predicate's two built-in ports are located on the mask.)
- ❑ Nosepiece has one pressure pickoff port. (Predicate elbow has two. Historically, the second pickoff port was not being used.)

Device Comparison (CONTINUED)

Modifications made to the headgear (Figure 3):

- The headgear consists of Velcro® straps. (The predicate headgear was a cap with Velcro® straps.)

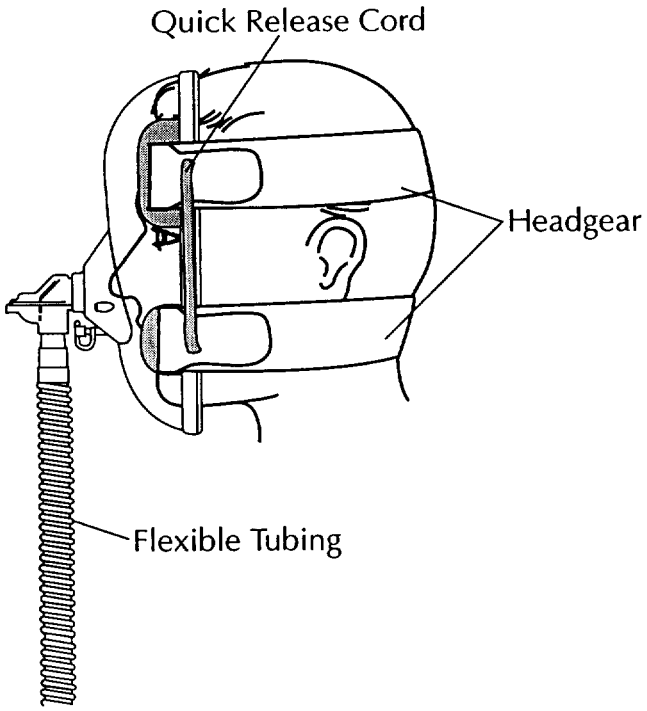


Figure 3. Respironics® Total™ Face Mask with headgear.

Substantial Equivalence

The modified mask has the following similarities to the previously cleared predicate device:

- Same intended use.
- Same operating principle.
- Same technology.
- Same manufacturing process.

In summary, the mask described in this submission is substantially equivalent to the predicate device.

Table 1 – Comparison of Devices

	Total Face Mask (K925920)	**Total Face Mask (Modified Device)**
Intended Use	Same.	
Operating Principle	Same.	
Patient Population	Same.	
Technology	Same.	
Manufacturing Process	Same.	
Provided Non-sterile	Same.	
Single Patient Use, Reusable	Same.	
Faceplate Material	Same.	
Cushion Design	Same.	
Shape and size of Faceplate	Larger, primarily round, with the exception of the eye area, which is squared off to allow a clearer field of vision.	Smaller, rounder, streamlined profile.
Exhalation Device	Exhalation ports on mask. Non-rebreathing valve (NRV) required for use.	Exhalation ports on nosepiece. Optional use of additional Respironics exhalation devices. Entrainment valve opens to ambient air if pressure should cease.
Number of Pressure Pickoff Ports	Two.	One.
Cushion Material	Urethane.	Silicone.
Mask Volume	2300 ml.	1550 ml.
Patient Circuit Connection	22-mm elbow. NRV has swivel that connects to 6-ft patient circuit.	22-mm entrainment valve. Valve has accessory swivel that connects to 6-ft. patient circuit.
Headgear	Cap with Velcro® straps.	Velcro® straps.

Continued on next page.

Summary of Design Control Activities

- The risk analysis method used to assess the impact of the re-design was a hazards analysis, consisting of identification of qualitative and quantitative characteristics related to the mask, identification of possible hazards, estimation of the risks for each hazard, determination of acceptability of risk, and risk reduction.
- The design verification tests that were performed as a result of this risk analysis assessment are listed in Table 2 **(on next page).**
- Test methods are the same as those used in the original 510(k) submission.
- A declaration of conformity with design controls is in Attachment 3.

510(k) Summary

A 510(k) Summary of Safety & Effectiveness is included in Attachment 4.

Truthful & Accuracy

A certification of the truthfulness and accuracy of the Total Face Mask described in this submission is provided in Attachment 5.

Please turn the page for "Table 2 – Verification Test Summary."

Table 2 – Verification Test Summary

(b)(4)Proprietary Information

[redacted]

(End of Section.)

ATTACHMENT 1

DRAFT LABELING

Draft Instructions for Use are included in this section. New promotional literature for the modified mask has not yet been generated. However, all claims will be consistent with those in this submission. There are no labels on the mask.

The text and graphics of the User Instructions reflect the modifications noted earlier in this submission, specifically:

- Non rebreathing valve (NRV) no longer required for use.
- Entrainment valve opens to ambient air if pressure should cease.
- Built-in exhalation ports located on nosepiece.
- Optional use of additional RI exhalation devices.
- Pressure pickoff port available.
- Accessory swivel for patient circuit connection.

(End of Section.)

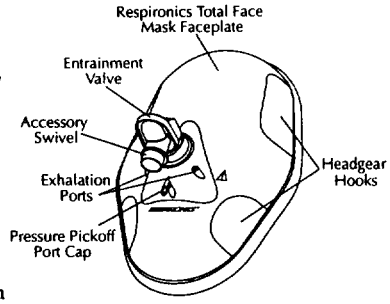
Respironics® Total™ Face Mask

Instructions for Use

Reorder #302433

LATEX-FREE

Single Patient Use Only



The Respironics Total Face Mask is intended to provide an interface for adult patients when used with Respironics CPAP or BiPAP® therapy. The mask contains exhalation ports that provide a continuous leak path in the patient circuit. This mask does not require the use of a separate exhalation device; however, you can use it with additional Respironics exhalation devices if you remove the accessory swivel.

Warnings

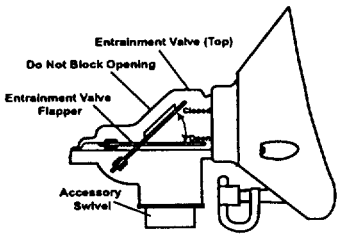
- The Respironics Total Face Mask is designed for use with CPAP and BiPAP systems recommended by your physician or respiratory therapist. Do not wear this mask unless the CPAP or BiPAP system is turned on and operating properly. Do not try to block or seal the exhalation ports in the mask.

  Most CPAP systems have the potential to allow rebreathing of exhaled air. CPAP systems are designed for use with masks (or connectors) that have vent holes or exhalation ports. When the CPAP system is turned on, new air from the system flushes the exhaled air out through the vent holes. If the CPAP system is not operating, the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.
- A minimum pressure of 5 cm H_2O must be maintained when using the Respironics Total Face Mask.
- System pressure and oxygen therapy may be different for a Respironics Total Face Mask than for a nasal or nasal/oral interface. When changing mask types, determine the appropriate pressure level and oxygen therapy. Because a small leak exists at the nose area of the mask and through the exhalation ports, you must ensure that the pressure and oxygen therapy are maintained against this higher leak level.
- When including an additional exhalation device to the patient circuit, you may need to adjust the pressure level to compensate for the additional leak of the exhalation device.
- The entrainment valve contains a magnet. Do not use this mask in or near magnetic resonance imaging (MRI) equipment.
- To minimize the risks of vomiting during sleep, the patient should avoid eating or drinking for three hours before use.
- The patient's physician should be contacted if the patient experiences the following symptoms while using the mask or after removing it: Unusual chest discomfort, shortness of breath, stomach distension, belching, or severe headache; drying of the eyes, eye pain, or eye infections; blurred vision (consult an opthamologist if symptoms persist).

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

Contraindications

This mask may not be suitable for use on patients with the following conditions: glaucoma, recent eye surgery or dry eyes, nocturnal vomiting, hiatal hernia, impaired cardiac sphincter function, or patients unable to remove the mask.



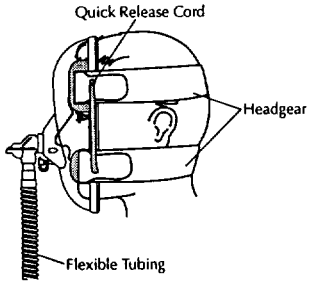
Verifying Entrainment Valve Function

With the unit turned off, the entrainment valve flapper (internal blue disk) should be open, allowing the user to breathe room air. Turn the unit On. The flapper should close, allowing the user to receive air flow from the unit. If the valve does not function in this manner, disassemble it, make sure the flapper is properly aligned, and reassemble. If the valve still does not function properly, notify your home care dealer. **Do not** block the opening on the entrainment valve. Check the valve before each use for dysfunction or any blockage by patient secretions. To ensure proper entrainment valve function, verify that the flapper is free moving and dry.

DRAFT

Connecting the Mask and Headgear

1. Set up the CPAP or BiPAP unit and patient circuit according to the unit's instruction manual.
2. To ensure a proper fit, place the patient's chin in the mask first, then lightly press the mask against the patient's face.
3. Pull the headgear straps around each side of the head and secure them to the mask. Do not overtighten the straps. Overtightening can cause or worsen leaks.
4. Connect the circuit tubing to the mask swivel. Turn the CPAP or BiPAP unit on.
5. Verify that there is only minor lifting of the mask from the patient's face (approximately 1/4" to 1/2") during a full respiratory cycle. Have the patient assume various sleeping positions (e.g., supine, lateral, prone) with the mask in place. Readjust the straps if necessary. If the inner flap covers the mouth, readjust the mask fit.



Removing the Mask and Headgear

To remove the mask quickly, pull on the quick release cord, away from the patient's face, and remove the mask. The mask and headgear can also be removed by detaching the headgear straps from the tabs on the mask.

Cleaning and Storage

Clean all parts of the mask daily. Clean the headgear at least once each week or more often if needed. Before cleaning, disconnect the mask and headgear.

Mask

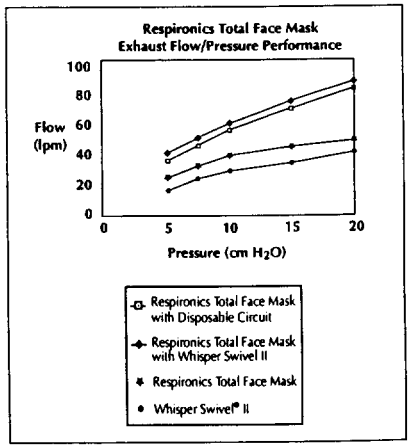
Do not use alcohol, cleaning solutions containing alcohol, or any strong household cleaners.

1. Hand wash the mask in warm water with a mild dishwashing detergent. Do not use cleaners containing moisturizers. Do not use bleach.
2. Rinse thoroughly. Air dry. Make sure the mask is dry before use. Replace the mask if any parts are damaged.

Headgear

1. Hand or machine wash with a standard laundry detergent and warm water. Rinse thoroughly. Do not use bleach.
2. Line dry or machine dry at the medium heat setting.

The mask should last approximately one year when cleaned according to these instructions.



Helpful Tips for Mask Comfort

- Clean the mask thoroughly before every use, including first-time usage.
- Clean the patient's face thoroughly before each use.
- Make sure the mask and headgear are the correct size for the patient's face. If excessive discomfort is experienced, have the mask readjusted or consider an alternative mask.
- Do not overtighten the headgear. Overtightening can irritate the patient's face, increase leaks, or cause damage to the cushion.

RESPIRONICS INC®
1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA

RESPIRONICS® Deutschland
Gewerbestrasse 17
82211 Herrsching Germany

CE 0123

1002964
JBM 7/30/99

ATTACHMENT 2

INDICATIONS FOR USE

Please turn the page.

(End of Section.)

510(k) Number (if known): _____

Device Name: Respironics® Total™ Face Mask

Intended Use/Indications for Use

The Respironics® Total™ Face Mask is intended to provide an interface for application of Respironics CPAP or BiPAP therapy to patients.

Environment of Use/Patient Population

For single patient use in the home or hospital/institutional environment. The mask is to be used on adult patients (>30 kg) for whom CPAP or BiPAP therapy has been prescribed using a Respironics CPAP or BiPAP system.

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number _____

ATTACHMENT 3

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Please turn the page.

(End of Section.)

RESPIRONICS®

1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA
Telephone: 1-724-733-0200
Fax: 1-724-387-5299

Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, the verification activities for the modification to the subject device, as required by the risk analysis, were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Elias Diacopoulos,
Product Development Manager

8/31/99
Date

Manufacturing Facility

To the best of my knowledge, the manufacturing facility, Respironics, Inc., Murrysville, PA, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the associated records are available for review.

Calvin W. Eggers,
Manager, Quality Assurance
Management Representative

9/2/99
Date

ATTACHMENT 4

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact	David J. Vanella Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Classification Reference	21 CFR 868.5905
Product Code	BZD – noncontinuous ventilator
Common/Usual Name	nasal mask
Proprietary Name	Respironics® Total™ Face Mask
Predicate Device	Total Face Mask (K925920)
Reason for submission	Modified design; modified materials.

Substantial Equivalence

The modified mask has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the Total Face Mask as a result of the risk analysis assessment, and acceptance criteria were met. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the mask described in this submission is substantially equivalent to the predicate device.

The modified mask complies with the applicable standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications," November 1993.

Device Description/Intended Use

The Total Face Mask is intended to provide a single-patient-use interface for adult patients (>30 kg) receiving Respironics CPAP or BiPAP therapy. The mask (Figure 1) fits over the entire face, with the rim of the mask framing the face along the hairline and jawline. The mask consists of a polycarbonate faceplate and a thin silicone cushion that folds inward, creating a flap on the inner perimeter of the mask to improve seal. The faceplate has four Velcro® hooks to which the headgear tabs attach.

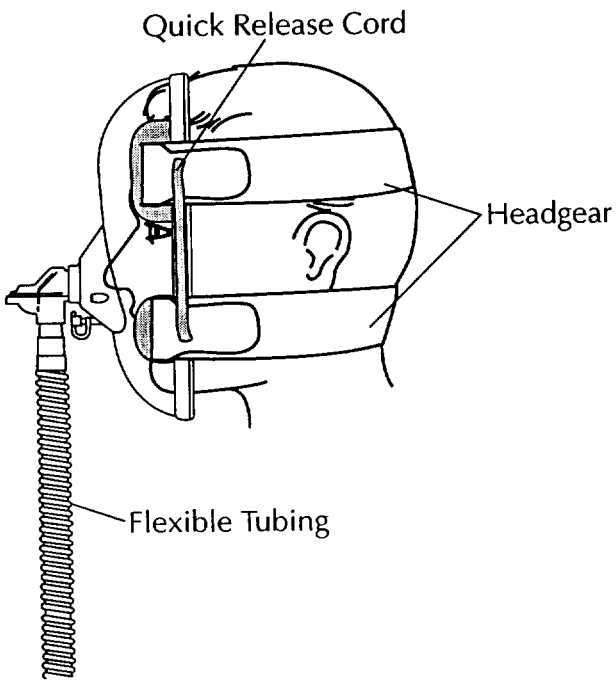


Figure 1. Respironics® Total™ Face Mask & headgear

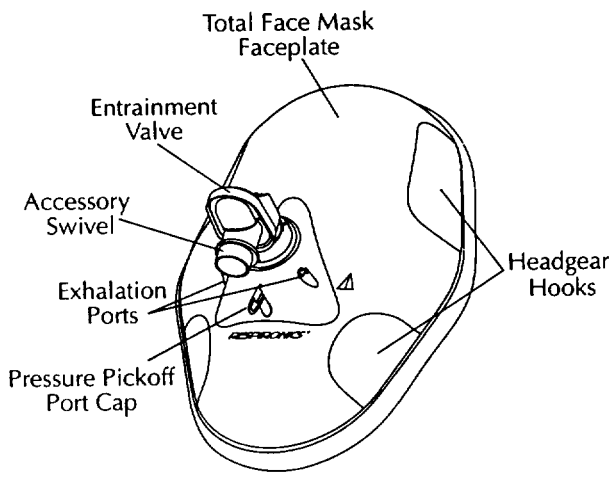


Figure 2. Respironics® Total™ Face Mask

The modified faceplate (Figure 2) is smaller, rounder, and has a streamlined profile. (Predicate mask is larger, primarily round, with the exception of the eye area, which is squared off.) Modified mask volume is smaller at 1550 ml. (Predicate volume is 2300 ml.) Modified mask cushion material is silicone. (Predicate cushion is urethane.)

Modified faceplate (Figure 2) has a nosepiece with 22-mm entrainment valve, whose accessory swivel connects to patient circuit. (Predicate faceplate has a 22-mm elbow, to which patient circuit is connected.) Entrainment valve opens to ambient air if pressure should cease. (Predicate requires use of a non-rebreathing valve (NRV).) Two built-in exhalation ports are located on the nosepiece. (Predicate's ports are located on the mask.) Nosepiece has one pressure pickoff port. (Predicate elbow has two.) The headgear consists of Velcro® straps. (Predicate headgear is a cap with Velcro straps.)

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ATTACHMENT 5

TRUTHFUL & ACCURACY

Please turn the page.

(End of Section.)

RESPIRONICS®

1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA
Telephone: 1-724-733-0200
Fax: 1-724-387-5299

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

Pursuant to 21 CFR 807.87 (j), I, David J. Vanella, certify to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Manager of Regulatory Affairs, and, in reliance thereupon, that the data and information submitted in this Premarket Notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.

D. J. Vanella

Mr. David J. Vanella
Manager, Regulatory Affairs

9/2/99
Date

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