



Food and Drug Administration
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September 18, 2015

Respironics, Inc.
Ms. Shaylee Masilunas
Regulatory Affairs Engineer
1001 Murry Ridge Lane
Murrysville, PA 15668

Re: K150639

Trade/Device Name: AF541 EE Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: August 14, 2015
Received: March 17, 2015

Dear Ms. Shaylee Masilunas:

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

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

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

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

 Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Enclosure

Indications for Use

510(k) Number (if known)

K150639

Device Name

AF541 EE Full Face Mask

Indications for Use (Describe)

AF541 EE Leak 1 Mask

This Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients (>40lbs/20kg) for whom CPAP or bi-level therapy has been prescribed.

AF541 EE Leak 2 Mask

This Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single use in the hospital/institutional environment and single patient use in the home. The mask is to be used on patients (>40lbs/20kg) for whom CPAP or bi-level therapy has been prescribed.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Summary

Date	March 9, 2015
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-7729 (724) 387-3999 (fax)
Official Contact	Shaylee Masilunas Regulatory Affairs Engineer
Establishment Registration #	2518422
Proprietary Name	AF541 EE Full Face Mask
Common/Usual Name	Mask Accessory to a Non-Continuous Ventilator
Classification Panel	Anesthesiology Devices
Classification Reference	21 CFR 868.5905
Classification Name / Product Code	BZD – Ventilator, non-continuous (respirator)
Predicate Device(s)	AF531 EE Full Face Mask (K101130)

Indications for Use**AF541 EE Leak 1 Mask**

The AF541 EE Leak 1 Full Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients (>40lbs/20kg) for whom CPAP or bi-level therapy has been prescribed.

AF541 EE Leak 2 Mask

The AF541 EE Leak 2 Full Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single use in the hospital/institutional environment and single patient use in the home. The mask is to be used on patients (>40lbs/20kg) for whom CPAP or bi-level therapy has been prescribed.

510(k) Summary

Device Description

The AF541 EE Full Face Mask is an oral-nasal full face mask that is available in various configurations (cushions and elbows). The AF541 EE Full Face has two cushion configurations, an Over the Nose (OTN) cushion and an Under the Nose (UTN) cushion. The following elbow configurations are available: EE Leak 1 and EE Leak 2. The Leak 1 and Leak 2 elbows have an anti-asphyxia valve. In addition, the Leak 2 elbow has built in exhalation to provide intentional leak when needed.

The AF541 EE Full Face Mask will have interchangeable cushions that attach to a common frame. There will be four sizes available for the over the nose option (S, M, L, XL). The UTN option will have three sizes available (A, B, C).

The AF541 mask will include a 4-point headgear and capstrap to allow for oral access with either headgear option. There will be 22 mm female mask frame. The AF541 OTN and UTN will be compatible with the EE Leak 1 and EE Leak 2 elbow.

Similarities and Differences of the Subject Device Compared to the Predicate Devices

The AF541 EE Full Face Mask has the following similarities to the previously cleared predicate devices AF531 EE Full Face Mask (K101130):

- Similar intended use
- Same operating principle
- Similar design
- Similar materials
- Similar manufacturing process

The AF541 EE Full Face Mask has the following differences in the technological characteristics to the previously cleared predicate devices AF531 EE Full Face Mask (K101130):

- Product Code
- Patient population
- Patient usage type
- Mask component design
- Mask materials

510(k) Summary

Table 1: Comparison Table of Respiroics AF541 EE Full Face Mask and predicate device

Area	Predicate Device AF531 EE Mask – Small Size (K101130)	Subject Device AF541 EE Full Face Mask
Overview		
<i>Intended Use</i>	<p><u>AF531 EE Leak 1 Mask</u></p> <ul style="list-style-type: none"> o The AF531 EE Leak 1 Full Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients 7 years or older (>40lbs/20kg) for whom CPAP or bi-level therapy has been prescribed. <p><u>AF531 EE Leak 2 Mask</u></p> <ul style="list-style-type: none"> o The AF531 EE Leak 2 Full Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients 7 years or older (>40lbs/20kg) for whom CPAP or bi-level therapy has been prescribed. 	<p><u>AF541 EE Leak 1 Mask</u></p> <p>This Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients (>40lbs/20kg) for whom CPAP or bi-level therapy has been prescribed.</p> <p><u>AF541 EE Leak 2 Mask</u></p> <p>This Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single use in the hospital/institutional environment and single patient use in the home. The mask is to be used on patients (>40lbs/20kg) for whom CPAP or bi-level therapy has been prescribed.</p>
<i>Patient Population</i>	7 years or older (>40lbs/20kg)	(>40lbs/20kg)
<i>Patient Usage Type / Environment of Use</i>	Single use in the hospital/institutional environment	EE Leak 1 - Unchanged from K101130. EE Leak 2 – Single use in the hospital/institutional environment and single patient use in the home.
<i>Product Code</i>	MNS	BZD The predicate device was classified with the Synchrony 2 BiPAP System as MNS. The AF531 and AF541 masks, as standalone devices, are classified under product code BZD.
<i>Provided Sterile or Non-Sterile</i>	Non-Sterile	Unchanged from K101130.

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Area	Predicate Device AF531 EE Mask – Small Size (K101130)	Subject Device AF541 EE Full Face Mask
<i>Anatomical Sites</i>	Nose and Mouth	Unchanged from K101130.
<i>Entrainment Valve</i>	The safety valve is integral to the mask and opens to atmosphere in the absence of therapy pressure.	Unchanged from K101130.
<i>Device Design</i>	<ol style="list-style-type: none"> 1. Faceplate/frame 2. Cushion 3. Elbow 4. Headgear 5. Headgear clips 	<ol style="list-style-type: none"> 1. Frame 2. Cushion 3. Elbow 4. Headgear 5. Headgear talon clips
<i>Sizes</i>	One size - Small	Over the Nose (OTN) version has four sizes (S, M, L, XL) Under the Nose (UTN) version has three sizes (A, B, C)

Table 2: Material comparison for the Respironics AF541 EE Full Face Mask and its predicate device

Component	Primary Predicate Device: AF531 EE Mask – Small Size K101130 Manufacturer: Respironics, Inc.	Subject Device: AF541 EE Full Face Mask Manufacturer: Respironics, Inc.
Cushion	Silicone	Silicone
Frame	Polycarbonate	Polycarbonate
Elbow	Polypropylene	Polypropylene
Entrainment Valve	Polycarbonate	Polypropylene
Headgear/Capstrap	Nylon/Spandex, Polyurethane Foam	Nylon/Spandex, Polyurethane Foam

New materials used in this mask are classified as external communicating, tissue contact, with a contact duration C (> 30 days cumulative). The following biocompatibility tests were completed:

- Muscle Implantation Study in Rabbits – 4 Weeks
- Muscle Implantation Study in Rabbits – 12 Weeks
- Genotoxicity: Bacterial Reverse Mutation Study
- Genotoxicity: Mouse Lymphoma Assay
- Genotoxicity: Mouse Peripheral Blood Micronucleus Study
- Intracutaneous Injection Test
- Kligman Maximization Test
- Agar Diffusion Test (Direct Contact)

510(k) Summary

Design verification tests were performed on the AF541 EE Full Face Mask. All tests were verified to meet the required acceptance criteria. Respirationics has determined that the modifications of the device have not raised new safety and effectiveness concerns. In summary, the device described in this submission is substantially equivalent to the predicate device.

Clinical Tests

Clinical tests were not required to demonstrate the substantial equivalence of the AF541 EE Full Face Mask. Product functionality has been adequately assessed by non-clinical tests.

Non-Clinical Tests

Performance testing was performed before and after cleaning treatments to verify that the device modifications of the subject device did not raise new safety and effectiveness concerns. Performance testing included:

- Total Mask Pressure Drop
- Total Mask Leak
- Intentional Leak
- Inspiratory & Expiratory Anti-Asphyxia Feature Resistance
- Anti-Asphyxia Feature Close to Atmosphere
- Anti-Asphyxia Feature Open To Atmosphere
- Dead space
- CO2 Rebreathing
- Storage - Temperature and Humidity
- Cleaning Validation

The AF541 EE Full Face Mask has been designed per the following standards:

- ISO 17510-2 Sleep Apnoea Devices Part 2: Masks and Application Accessories
 - Deviation
 - Clause 5.3 Protection Against Rebreathing
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 14971 Medical devices – Application of risk management to medical devices

Conclusion

The performance and technological characteristics of the AF541 EE Full Face Mask are substantially equivalent to those of the AF531 EE Full Face Mask (K101130). The differences described above do not raise new questions of safety and effectiveness.