TAB 3

K101129

SEP 13 2010

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Date of Submission	April 21, 2010
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Official Contact	Zita Yurko Director, Regulatory Affairs (724) 387-4120 (724) 882-4120 (cell) (724) 387-4216 (fax)
Proprietary Name	Respironics AF531 SE Full Face Mask
Common/Usual Name	Face mask
Classification	Class II Device
Classification Panel	Anesthesiology Devices
Product Code	CBK – Continuous ventilator
Predicate Devices	Respironics PerforMax SE Total Face Mask (K072588/K092648)
Labeling	Draft labeling can be found in Tab 5
Reason for submission	Modified device

Device Description

The Respironics AF531 SE Full Face Mask consists of a silicone cushion, polycarbonate faceplate with a standard elbow with no exhalation, requiring the use of a separate exhalation device. This mask is an accessory for use with ventilators in the hospital/institutional environment only. The small size AF531 SE Full Face Mask will be used on patients 7 years or older (> 40 lbs/20kg).

Intended Use

The small size AF531 SE Full Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or

positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea. 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) who are appropriate candidates for noninvasive ventilation.

Predicate Comparison

Comparison of the AF531 SE Full Face Mask (modified mask) with the predicate Respironics PerforMax SE Total Face Mask (K072588/K092648);

- The intended use and the environment of use is the same. Both masks are for the hospital/institutional use only on patients 7 years or older and > 40lbs/20kg.
- Both masks contain a silicone cushion, polycarbonate faceplate and standard elbow, requiring the use of an additional exhalation device. The same elbow is on both masks.
- Both masks use the same headgear (Four Points Headgear design) and headgear attachment clips. The CapStrap headgear may also be used with the AF531 mask.
- The difference between the modified device and the Respironics PerforMax SE Total Face Mask predicate is the shape of the faceplate and cushion. The modified device is a full face mask with a faceplate and cushion covering the nose and mouth, whereas the predicate device is a total face mask with a faceplate and cushion covering the nose, mouth and eyes.

The modified device has been performance tested with passing results. Test protocols including pressure performance, waveform performance, triggering, cycling and alarm functionality testing along with the results of these tests are provided in Tab 8 of this submission.

Substantial Equivalence

The AF531 SE Full Face Mask has the following similarities to the previously cleared predicate device:

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

There is no change to the intended use, operating principle, technology or manufacturing process for the AF531 SE Full Face Mask. The small size AF531 SE Full Face Mask was performance tested

and verified to meet the required acceptance criteria. Results of this testing concluded that the verification testing raises no new issues of safety or effectiveness.

Respironics has followed the FDA's Guidance for Industry and FDA Staff document "pre-market assessment of pediatric medical devices" and applied the principle of FDA's Least Burdensome Approach to demonstrate the Substantial Equivalence of the mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Respironics, Incorporated
Ms. Zita A. Yurko
Director, Regulatory Affairs
Sleep & Home Respiratory Group
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

SEP 1 3 2010

Re: K101129
Trade/Device Name: AF531 SE Full Face Mask
Regulation Number: 21 CFR 868.5895
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: August 12, 2010
Received: August 18, 2010

Dear Ms. Yurko:

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

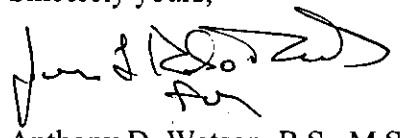
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

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

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

Sincerely yours,



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

Enclosure

Indications for Use

K101129

SEP 13 2010

510(k) Number (if known): _____

Device Name: AF531 SE Full Face Mask

The small size AF531 SE Full Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea. 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) who are appropriate candidates for noninvasive ventilation.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K101129