TAB 1

510(K) SUMMARY OF SAFETY & EFFECTIVENESS / EXECUTIVE SUMMARY

JAN 03 2003

RESPIRONICS INC.
1001 Murry Ridge Lane, Murrysville, PA 15668

Date of Submission	September 13, 2002
Official Contact/ Address Of Manufacturing Facility	Zita A. Yurko Manager, Regulatory Affairs Phone: (724) 387-4120 Fax: (724) 387-4216 Email: Zita.Yurko@Respironics.com Respironics Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Establishment Registration Number	2518422
Proprietary Name	Image3 SE Disposable Full Face Mask
Common/Usual Name	Face Mask
Classification Reference	21 CFR 868.5895
Class	Class II
Classification Panel	Anesthesiology Devices
Product Code	CBK – Ventilator, Continuous
Predicate Device	Spectrum 2 Full Face Mask (K002465)
Reason for submission	Modified design

The Image3 SE Disposable Full Face Mask is available in three sizes: small, medium, and large, and is only indicated for use on adult patients.

A typical patient circuit consists of tubing and possibly a humidifier, and/or bacteria filter.

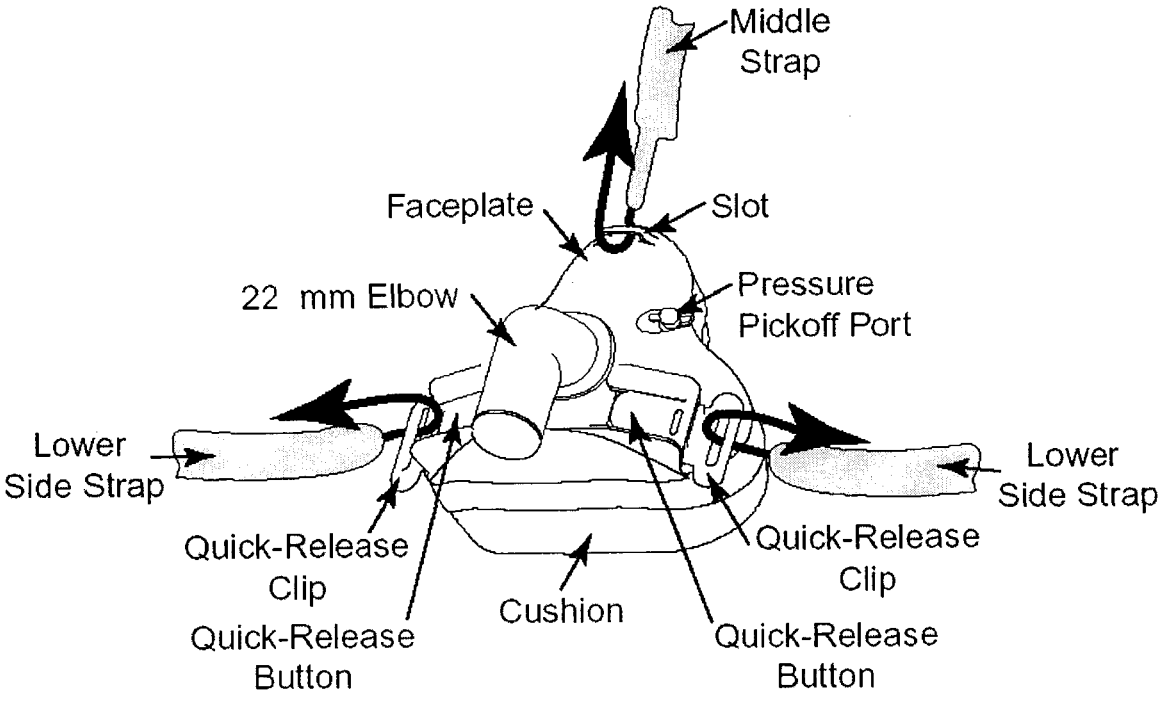

Figure 1-1: Image3 SE Disposable Full Face Mask

(End of Section.)

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device, the Spectrum 2 Full Face Mask (K002465):

- ❑ Same operating principle
- ❑ Same technology
- ❑ Same manufacturing process

Design verification tests were performed on the Respironics Image3 SE Disposable Full Face Mask as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate device.

Indications for Use

The Image3 SE Disposable 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 ventilator 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 disposable and for single patient use. It is intended for use on adult patients (> 30 kg), who are appropriate candidates for noninvasive ventilation, in the hospital/institutional environment only.

Device Description

The Image3 SE Disposable Full Face Mask is an externally placed mask covering the nose and mouth (full face) of a patient. It is intended to provide a seal so that positive pressure from a positive pressure source is directed to the patient's nose and mouth. The device consists of a faceplate, standard elbow, cushion, and headgear. The faceplate has one pressure pick off/oxygen enrichment port with port cap, a slot at the top of the faceplate to attach a headgear strap, and two integrated headgear quick release clips (one each side of the faceplate) for fast and easy removal of the mask.

Please refer to Figure 1-1 for an illustration of the mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 3 2003

Ms. Zita A. Yurko
Manager, Regulatory Affairs
Respironics, Incorporated
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550

Re: K023135
Trade/Device Name: Image3 SE Disposable Face Mask
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: December 23, 2002
Received: December 24, 2002

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023135

Device Name: Image3 SE Disposable Full Face Mask

Indications for Use:

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(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: K023135

(Optional Format 3-10-98)