AUG 21 2009

Section iv - 510 (k) Summary

[Refer to 21 C.F.R § 807.92]

Submitted by: Respironics Novametrix, LLC
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Wallingford, CT 06484

Contact Person: Kevin Mader
Q.A. and Regulatory Manager
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Date Prepared: 7/20/2009

Proprietary Name: Mercury Module with Capnostat 5 CO_2 sensor

Common Name: spirometer with CO_2 sensor

Classification Name: Class II, 21 CFR 868.1850 and 868.1400

Predicate Device: Mercury Module with Capnostat 5 CO_2 sensor (K080652)

Description of Device: The Mercury module with Capnostat 5 is intended for non-invasive monitoring of the inspired and expired airflow and airway pressure of intensive care unit (ICU), anesthesia and emergency room (ER) patients, as well as capnography in all of these clinical settings. It is intended to serve the same purposes as the Mercury module with Capnostat 5.

Intended Use of the Device: Mercury Module with Capnostat 5 CO_2 sensor has the same intended use as the predicate device. For reference, the intended use of the Mercury Module with Capnostat 5 CO_2 sensor is to provide spirometric, and carbon dioxide monitoring in neonatal, pediatric and adult patients during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED).

Technological Characteristics The submitted Mercury module with Capnostat 5 is identical to the cleared Mercury Module with Capnostat 5 CO_2 sensor. except the nominal upper limit for the specification for the neonatal flow and neonatal CO2/flow sensors used with the Mercury module has been increased from 25 to 30 LPM to align with the specification for maximum inspiratory flow for ventilators cleared for use with neonates. The Mercury module with Capnostat 5 is intended to provide continuous monitoring of respiratory flow and pressure, and CO_2 during anesthesia and intensive care and in the emergency department. The flow sensors connect to a patient airway circuit and provide physiological information to the Mercury module. The parameters directly measured and computed by the module (when connected to a Capnostat 5 sensor) include airway flow and pressure, volume, and CO_2. The monitor calculates flow by measuring the pressure drop across a known resistance placed in the breathing circuit. CO_2 is measured as the absorption of a known intensity of infrared light by CO_2 molecules in the airway.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

AUG 21 2009

Mr. Kevin Mader
Manager of Quality Assurance and Regulatory Affairs
Respironics Novametrix, Incorporated
5 Technology Drive
Wallingford, Connecticut 06492-1950

Re: K092217
Trade/Device Name: Mercury Module with Capnostat 5
Regulation Number: 21 CFR 868.1850
Regulation Name: Monitoring Spirometer
Regulatory Class: II
Product Code: BZK, CCK
Dated: July 20, 2009
Received: July 22, 2009

Dear Mr. Mader:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Section ii
Indications for Use

510(k) Number (if known): K092217

Device Name: Mercury Module with Capnostat 5

Indications for Use:

The intended use of the Mercury module with Capnostat 5 is to provide:

- spirometric, and carbon dioxide monitoring in neonatal, pediatric and adult patients during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED). Separate combination CO_2/flow sensors are provided for adult, pediatric and neonatal use.

Prescription Use _____x_____ (Per 21 CFR 801 Subpart D) AND/OR Over-The -Counter Use _____ (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)

L Schutter

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

510(k) Number: K092217

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