K042601

NOV 19 2004

Section iv - 510 (k) Summary

[Refer to 21 C.F.R § 807.92]

Submitted by: Respironics Novametrix, LLC
5 Technology Drive
Wallingford, CT 06492

Contact Person: Kevin Mader
Q.A. and Regulatory Manager
Phone: 203-697-6466

Date Prepared: 9/22/2004

Proprietary Name: Capnostat 5 CO_2 sensor

Common Name: CO_2 sensor

Classification Name: Class II, 21 C.F.R 868.1400

Predicate Device: Capnostat III sensor in Tidal Wave Sp, Model 710/715 [510(k) K032971]

Description of Device: The Capnostat 5 CO_2 sensor is designed for continuous, non-invasive monitoring of carbon dioxide.. Carbon dioxide is measured on-airway using an infrared absorption (IR) technique. The airway adapters are already legally marketed as accessories to the predicate device. The Capnostat 5 CO_2 sensor is an integrated microprocessor based data acquisition system consisting of CO_2 measurement, control circuitry and a high speed serial interface. The Capnostat 5 CO_2 sensor uses SRAM for data storage and an EEPROM to store system parameters. The firmware resides in a PROM. The operations performed by the Capnostat 5 CO_2 sensor include data acquisition, parameter calculation, zeroing, heater control and corrections to the CO_2 signal for N_2O, O_2 and barometric pressure.

Intended Use of the Device: This sensor has the same intended use as the predicate device. For reference, the intended use of the Capnostat 5 CO_2 sensor is to provide carbon dioxide monitoring to a host monitoring system during anesthesia / recovery, in the intensive care unit (ICU), and in Emergency Medicine/Transport or Respiratory care.

Technological Characteristics:. Capnostat 5 CO_2 sensor is a mainstream CO_2 sensor that attaches to an airway adapter (also referred to as a cuvette) and in which the patient's inspired and expired breath passes. The airway adapter is attached to a mouthpiece or mask, or to the breathing circuit between the endotracheal tube and ventilator circuit wye, if the patient is intubated. It is designed to use neonatal and adult CO_2 airway adapters. The Capnostat CO_2 sensor uses an infrared absorption (IR) technique for monitoring CO_2. IR based methods have endured and evolved in the clinical setting for over two decades, and remain the most popular and versatile technique today. The principle is based on the fact that CO_2 molecules

absorb infrared light energy at specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When the IR light beam is passed through a gas sample containing CO_2, the electronic signal from the photodetector can be obtained. This signal is then compared to the energy of the IR source, and calibrated to accurately reflect CO_2 concentration in the sample. To calibrate, the photodetector's response to a known concentration of CO_2 is stored in the monitor at the factory. Solid state CO_2 sensors (such as the Capnostat) use a beam splitter to simultaneously measure the IR light at two wavelengths: one which is absorbed by CO_2 and one which is not. The wavelength which is not absorbed by CO_2 is related to the intensity of the IR light source. Also, the IR light source is electronically pulsed (rather than interrupting the IR beam with a chopper wheel) in order to eliminate effects of changes in electronic components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2004

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

Re: K042601
Trade/Device Name: Capnostat 5 CO_2 Sensor
Regulation Number: 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: November 1, 2004
Received: November 2, 2004

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.

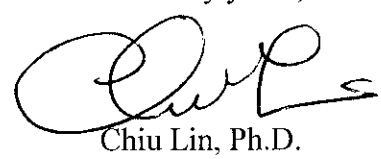
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
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): K042601

Device Name: Capnostat 5 CO_2 Sensor

Indications for Use:

The intended use of the Capnostat 5 CO_2 sensor is to provide carbon dioxide monitoring to a host monitoring system during anesthesia / recovery, in the intensive care unit (ICU), and in Emergency Medicine/Transport or Respiratory care.

Prescription Use _____X_____ AND/OR Over-The -Counter Use _____
(Per 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

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