JUN 1 8 2004

K041450

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: 5/28/2004

Proprietary Name: NICO with MARS, Model 7300, monitor with NICO to Esprit Communications Interface

Common Name: multiparameter monitor (monitoring spirometer, CO_2 monitor, pulse oximeter and cardiac output monitor with partial rebreathing valve).

Classification Name: Class II, 21 C.F.R. 868.1850, 868.1400, 870.2700, 868.5675

Predicate Device: NICO with MARS, Model 7300 [510(k) K030886]

Description of Device: The NICO with MARS, Model 7300, is a patient monitor capable of monitoring a patient's cardiac output, spirometry, carbon dioxide, and functional oxygen saturation and pulse rate. In addition, the Model 7300 is capable of communicating with a variety of patient information systems, including the Respironics Esprit ventilator.

Intended Use of the Device: This monitor has the same intended use as the predicate monitor. For reference, the intended use of the NICO with MARS, Model 7300, monitor is to provide:

- cardiac output monitoring via the method of partial rebreathing in adult patients receiving mechanical ventilation during general anesthesia and in the intensive care unit (ICU).
- 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.
- continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients during both no motion and motion conditions and for patients who are well or poorly perfused during general anesthesia and in the intensive care unit (ICU) and the emergency department (ED).

The use of the NICO with MARS, Model 7300, monitor for cardiac output monitoring is contraindicated in patients in which a small rise (3-5 mmHg) in their arterial partial pressure of CO_2 level cannot be tolerated.

Technological Characteristics: The NICO with MARS monitor, Model 7300, uses flow sensors that are considered to be a fixed orifice, target flowmeters and as such the pressure drop is proportional to the square of the flow. Combination CO_2/flow sensors are available in three flow ranges that are tailored for neonates, pediatric patients and adults.

The NICO with MARS monitor, Model 7300, uses an infrared absorption (IR) technique for monitoring CO_2. The principle is based on the fact that CO_2 molecules absorb infrared light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration 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.

The NICO with MARS monitor, Model 7300, measures oxygen saturation and pulse rate with sensors that contain red and infrared light sources. Since oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared with unsaturated blood, the amount of light absorbed at each wavelength by the blood in each pulse can be used to calculate oxygen saturation. The light energy from red (660 nm) and infrared (940 nm) LEDs is beamed through a pulsating vascular bed - the patient's finger, ear or toe, for example. The remaining light energy not absorbed by the sample cell reaches a photodiode, on the opposing side of the sensor. The signal received by the photodiode is split into its red and infrared components, sampled, software filtered and displayed as a numerical value for oxygen saturation and pulse rate and as a waveform, the plethysmogram.

Functional saturation represents the amount of oxyhemoglobin as a percentage of the hemoglobin that can be oxygenated. Dysfunctional hemoglobin (COHb and METHb) are not included in the measurement of functional saturation. Pulse rate is calculated by measuring the time interval between the peaks of the infrared light waveform. The *NICO with MARS* must be used in conjunction with the Novametrix SuperBright™ series of oxygen saturation sensors. MARS technology uses the computational power of digital signal processing to replace the pulse rate interval and rate-based decision tree algorithm of prior devices with a more robust frequency-based algorithm.

A variation on the traditional rebreathing methods, the non-invasive differential Fick partial re-breathing technique is used in the NICO with MARS monitor. The change in VCO_2 and the change in end-tidal CO_2 in response to a change in ventilation is used to determine pulmonary capillary blood flow. This value is then corrected for the effect of shunt to determine cardiac output.

The NICO with MARS monitor communicates with external devices via bi-directional serial communications. Essentially the serial port communicates parameters, real-time waveforms of flow, pressure and CO_2 and error message strings comprised of a mix of ASCII characters and scaled binary digits. Analog outputs are also provided for connections to chart recorders and other equipment. Supported communication interfaces include ASCII character output, the GE Solar monitor, Philips VueLink/Viridia, Spacelabs Flexport, Nellcor Model N-395, and the Respironics Esprit Ventilator. The monitor is also capable of printing trend graphs to an H.P.-compatible printer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2004

Mr. Kevin Mader
QA and Regulatory Manager
Respironics Novametrix, LLC
5 Technology Drive
Wallingford, CT 06492

Re: K041450
Trade/Device Name: NICO with MARS, Model 7300
Regulation Number: 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: May 28, 2004
Received: June 1, 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 (301) 594-4646. 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): K041450

Device Name: NICO with MARS, Model 7300 with NICO to Esprit Communications Interface

Indications for Use:

The intended use of the NICO with MARS, Model 7300, monitor is to provide:

- cardiac output monitoring via the method of partial rebreathing in adult patients receiving mechanical ventilation during general anesthesia and in the intensive care unit (ICU).
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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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