OCT - 7 2003

K030886

510(K) SUMMARY

July 11, 2003

a. Applicant's Name and Address

Respironics Novametrix Inc.
5 Technology Drive
Wallingford, CT 06492

b. Contact Person

Michael J. Malis
Q.A. and Regulatory Manager
(203) 697-6442
(203) 284-0753 (facsimile)

c. Name of Device

Device Names (Proprietary/Trade Names):	NICO, Model 7300
Device Name (Common Name):	multiparameter monitor (monitoring spirometer, CO_2 monitor, pulse oximeter and cardiac output monitor with partial rebreathing valve).
Classification:	Class II, 21 C.F.R. 868.1850, 868.1400, 870.2700, 868.5675

d. Equivalent Devices

Substantial equivalence to the following legally marketed predicate devices with the same or similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for predicate devices and for the Model 7300, as well as testing to accepted industry standards. In addition, controlled hypoxia studies were conducted to establish the Model 7300 pulse oximetry accuracy and to ensure that the sensors meet their currently published accuracy specifications with the Model 7300. The predicate devices are as follows:

1. CO2SMO Plus! with NICO, Model 8200 (K982499)
2. MARSPO2, Model 2001 (K993979, K000794).

e. Device Description

The NICO monitor Model 7300 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 and pulse oximetry in all of these clinical settings. As is its predicate device *CO_2SMO Plus! with NICO, NICO with MARS* is designed to use neonatal, pediatric, and adult combined CO_2/flow sensors and single patient use or reusable pulse oximetry sensors. It non-invasively calculates cardiac output using established physiological principles by the application and removal of a rebreathed volume in a patient's breathing circuit and the analysis of that response. The *NICO with MARS* is intended to provide cardiac output monitoring in mechanically ventilated patients in the operating room and intensive care units. It is intended to serve the same purposes as the CO_2SMO Plus! with NICO and MARSPO$_2$, Model 2001.

Oxygen saturation is measured with ratiometric technique using red and infrared absorbance of oxy- and deoxyhemoglobin and pulse rate is measured using the time between successive pulses. The O_2 saturation sensors are already legally marketed as accessories to the Model 2001 monitor. As the Model 2001 monitor, the Model 7300 with MARS consists of a dual microprocessor based data acquisition system that measures oxygen saturation data. The firmware for the second microprocessor, a digital signal processor, performs the filtering, pulse rate and saturation calculations of the existing algorithms and additional calculations which analyze the incoming signals and perform noise reduction on that signal when the presence of noise is detected.

The Model 7300 can be powered by either an internal power supply operating on AC or by a sealed rechargeable lead-acid gel battery. Audible and visual alarms for high/low saturation and pulse rate are available. There is also a serial port that provides user configurable data output capable of communicating with printers and other devices.

f. Intended Use

The intended use of the NICO monitor, Model 7300 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 monitor Model 7300 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. The intended use, patient population and environments of use are the same or similar to the predicate devices, CO_2SMO Plus! with NICO, Model 8200 and MARSPO_2, Model 2001

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g. Technological Characteristics

The *NICO with MARS* 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* 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* 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 sample cell- a pulsating vascular bed, the patient's finger 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 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 exploits the computational power of the 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.

h. Certification Statement

In accordance with the requirements of 21 CFR 807.87(j), the following certification is provided:

Respironics Novametrix, Inc. believes that all data and information submitted in this premarket notification are truthful and accurate and no material fact has been omitted.

M. Malis 7/10/03

Michael J Malis
Q.A. and Regulatory Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 7 2003

Mr. Michael Malis
Regulatory and QA Manager
Respironics Novametrix Incorporated
5 Technology Drive
Wallingford, CT 06492

Re: K030886
Trade/Device Name: NICO with MARS, Model 7300
Regulation Number: 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer, Gaseous-Phase
Regulatory Class: II
Product Code: CCK, BZK, DQA
Dated: July 11, 2003
Received: July 14, 2003

Dear Mr. Malis:

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

510(k) Number (if known): K030886

Device Name: NICO with MARS

Indications For Use:

The intended use of the NICO monitor, Model 7300 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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- 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).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K030886

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)