AUG 2 3 2004

K032949

510(K) SUMMARY

July 27, 2004

a. Applicant's Name and Address

Respironics Novametrix, Inc.
5 Technology Drive
Wallingford, CT 06492

b. Contact Person

Kevin Mader
Q.A. and Regulatory Manager
(203) 697-6466
(203) 284-0753 (facsimile)

c. Name of Device

Device Names (Proprietary/Trade Names):	Models 512/513 Pulse Oximeter
Device Name (Common Name):	Pulse Oximeter
Classification:	Class II, 21 C.F.R. 870.2700 /74DQA

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 the Model 512/513, as well as testing to accepted industry standards. In addition, inter-device comparison studies were conducted to establish the Model 512/513s accuracy and to ensure that the sensors meet their currently published accuracy specifications with the Model 510. The predicate device is as follows:

1. Model 510 Pulse Oximeter, Novametrix Medical Systems, Inc., K924626

e. Device Description

The Model 512/53 Pulse Oximeters are designed for non-invasive measurement of the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. 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 510 monitor. The Model 510 displays digital values of SpO_2 and pulse rate. The Model 512/513 consists of a microprocessor based data acquisition system that measures oxygen saturation data. The Model 513 also contains additional circuitry to support battery backed trend data storage and retrieval. Data is stored in a 16Kbyte serial Flash RAM, with time and date retrieved from a separate serial real time clock. The trend data may be transferred serially to a printer or PC via an IRDA compatible chipset.

f. Intended Use

The Model 512 Handheld Pulse Oximeter is intended to provide non-invasive spot checking of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients in hospital, hospital-type facilities and intra-hospital transport. The Model 513 Handheld Pulse Oximeter is intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients in hospital, hospital-type facilities and intra-hospital transport. The monitor and its sensors are intended to be used by trained operators when pulse oximetry monitoring is required in the judgment of a licensed medical practitioner. The intended use, patient population and environments of use are the same or similar to the predicate device, the Novametrix Model 510

g. Technological Characteristics

The Model 512/513 Pulse Oximeters measure functional 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 and infrared 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, processed using proprietary algorithms and displayed as a numerical value for functional oxygen saturation and as a waveform, the plethysmogram.

The Models 512/513 use the identical SpO_2 and pulse rate software algorithm to process the information from the sensor as the predicate device, Model 510 Pulse Oximeter, cleared under K924626.

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.

Kevin Mader
Q.A. and Regulatory Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2004

Mr. Michael J. Malis
Quality Assurance and Regulatory Manager
Respironics Novametrix, Incorporated
5 Technology Drive
Wallingford, Connecticut 06492

Re: K032949
Trade/Device Name: Model 512/513 Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 4, 2004
Received: August 5, 2004

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):_____

Device Name: Model 512/513 Pulse Oximeter

Indications For Use:

The Model 512 Handheld Pulse Oximeter is intended to provide non-invasive spot checking of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients in hospital, hospital-type facilities and intra-hospital transport.

The Model 513 Handheld Pulse Oximeter is intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate in neonatal, pediatric and adult patients in hospital, hospital-type facilities and intra-hospital transport.

The monitor and its sensors are intended to be used by trained operators when pulse oximetry monitoring is required in the judgment of a licensed medical practitioner

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(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: K072949

(Optional Format 1-2-96)