FEB 22 2000

K993979

## 510(K) SUMMARY

November 17, 1999

a. Applicant's Name and Address

Novametrix Medical Systems, Inc.
5 Technology Drive
Wallingford, CT 06492

b. Contact Person

Robert H. Schiffman, R.A.C.
Q.A. and Regulatory Manager
(203) 284-2542
(203) 284-0753 (facsimile)

c. Name of Device

| | |
|---|---|
| Device Names (Proprietary/Trade Names): | Model 2001 MARS$pO_2$ 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 predicate devices and for the Model 2001, as well as testing to accepted industry standards. In addition, inter-device comparison studies and non-invasive controlled hypoxia studies were conducted to establish the Model 2001 accuracy and to ensure that the sensors meet their currently published accuracy specifications with the Model 2001. The predicate devices are as follows:

1. Model 520A Pulse Oximeter, Novametrix Medical Systems, Inc., K913516
2. Model 2000 Pulse Oximeter, Ivy Biomedical Systems, Inc., K982255
3. N-395 Pulse Oximeter, Nellcor Puritan Bennett Inc., K991823

e. Device Description

The Model 2001 Pulse Oximeter is designed for continuous, non-invasive monitoring 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 520A monitor. The Model 2001 displays digital values of $SpO_2$ and pulse rate as well as a graphic display of the plethysmogram. The Model 2001 monitor consists of a dual microprocessor based data acquisition system that measures oxygen saturation data. The firmware for the primary microprocessor performs the functions of the existing Model 520A including data acquisition, display, trending and communications with external devices. 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 2001 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. The Model 2001 also includes a temporary (2 minute) and permanent alarm silence and other configurable settings. The Model 2001 provides an audible low battery warning to alert the user of impending loss of power and consequent loss of monitoring capability. The Model 2001 Pulse Oximeter has visual indicators for pulse error conditions, power mode (i.e. AC vs. battery) and alarm silence. There is also a serial port that provides user configurable data output capable of communicating with printers and other devices.

f. Intended Use

The Model 2001 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 environments such as the operating room, emergency department and intensive care units. The Model 2001 Pulse Oximeter and its sensors are intended to be used by trained operators when pulse oximetry monitoring is required in the judgement of a physician. The intended use, patient population and environments of use are the same or similar to the predicate devices, the Novametrix Model 520A Pulse Oximeter, Ivy Biomedical Model 2000 Oximeter, and the Nellcor Puritan Bennett N-395 Pulse Oximeter.

g. Technological Characteristics

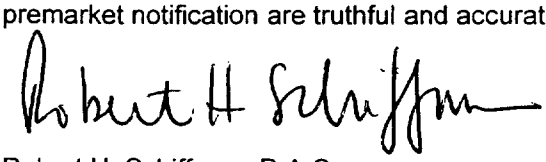
The Model 2001 Pulse Oximeter measures functional oxygen saturation and pulse rate with sensors that contain red and infrared light sources. Since oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared with unsaturated blood, the amount of light absorbed 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 plethysogram.

The Model 2001 uses a similar $SpO_2$ and pulse rate software algorithm to process the information from the sensor as the predicate device, Model 520A Pulse Oximeter, cleared under K913516. In addition, the Model 2001 possesses artifact filtering software that reduces the effects of artifact such as patient/sensor motion. This allows the Model 2001 to provide valid $SpO_2$ and pulse rate readings for increased levels of artifact as compared to previous generations. With this capability the Model 2001 provides a decrease in false/nuisance alarms due to the effect of motion artifact.

h. Certification Statement

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

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



Robert H. Schiffman, R.A.C.
Q.A. and Regulatory Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2000

Mr. Robert H. Schiffman
Novametrix Medical Systems, Inc.
5 Technology Drive
P.O. Box 690
Wallingford, CT 06492-1926

Re: K993979
Model 2001 MARSp$O_2$
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: November 17, 1999
Received: November 24, 1999

Dear Mr. Schiffman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): k993979

Device Name: Model 2001 Pulse Oximeter

**Indications For Use:**

The Model 2001 Pulse Oximeter is intended to provide continuous, non-invasive monitoring of functional arterial oxygen saturation and pulse rate units in neonatal, pediatric and adult patients in hospital, hospital-type facilities and intra-hospital transport environments such as the operating room, emergency department and intensive care units. The Model 2001 and its sensors are intended to be used by trained operators when pulse oximetry monitoring is required in the judgement of a physician.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of Cardiovascular, Respiratory and Neurological Devices

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

510(k) Number _____

**(Optional Format 1-2-96)**