K982255

OCT 22 1998

510(K) SUMMARY

Submitted by: Ivy Biomedical Systems, Inc.
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Company Contact: Dick Listro, Regulatory Affairs/Quality Assurance

Date Summary Prepared: September 22, 1998

Trade Name: Model 2000 Pulse Oximeter

Common Name: Pulse Oximeter

Classification Name: Oximeter (74DQA)

Substantially Equivalent Devices: Masimo SET® MS-1P Pulse Oximeter and accessories 510K# K973887.

Description of Model 2000 Pulse Oximeter

The Model 2000 pulse oximeter is a device consisting of the Masimo SET® technology (license to Ivy Biomedical), Masimo connecting cable, and Masimo oximetry sensors to nonivasively calculate the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It features an easy-to-read LCD display that presents patient data and status information.

Features

- Several types of Masimo LNOP® sensors for flexibility.
- Automatic alarm messages.
- Backlit and adjustable contrast display for excellent visibility in subdued lighting conditions.
- Direct access to user-selectable high and low alarm limits for SpO_2 and pulse rate.
- An audible pulse indicator with an adjustable volume; the automatic pitch modulation reflects changing SpO_2 level.
- Visual and audible (adjustable volume) alarms.
- An alarm-silence feature; silences audible alarms continuously until deactivated.
- Status and alarm informational messages appear on the LCD.
- Short, medium, or long SpO_2 response averaging modes (4 to 16 seconds).
- Automatic storage of up to 8 hours of SpO_2 in trend memory.
- Larger SpO_2 digital display for clear differentiation from the pulse rate value.

The Masimo PC series connecting cables connects the monitor to the oximetry sensors and transfers LED drive power and the calibration drive to the oximetry sensors from the monitor and the monitor receives the detector signal from the oximetry sensor.

The Masimo LNOP® series of oximetry sensors measure the light absorption of blood from two light emitting diodes (LED's). Oxygen saturated blood absorbs light differently as compared to unsaturated blood. The amount of light absorbed by the blood is used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood.

Intended use

The intended use of the Model 2000 pulse oximeter is the continuous noninvasive monitoring of functional saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by a SpO_2 sensor) for adult, pediatric and neonatal patients in a hospital and mobile environment (within the hospital).

Indication for use

Model 2000 pulse oximeter and the Masimo LNOP® Series of Sensors and Masimo PC Series of Patient Cable are indicated for the continuous noninvasive monitoring of arterial oxygen saturation (SpO_2) and pulse rates for adult, pediatric and neonatal patients in a hospital and mobile environment (within the hospital).

In addition the Model 2000 is indicated for the continuous non-invasive monitoring of arterial oxygen saturation (SpO_2) and pulse rates for adults during patient motion conditions.

Principles of operation

The principles of operation of the Model 2000 pulse oximeter is that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography), and that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption the amount of red and infrared light absorbed by the blood is related to hemoglobin oxygen saturation. The Masimo SET® module in the Model 2000 pulse oximeter decomposes the red and infrared pulsatile absorbance signal into an arterial signal plus a noise component and calculates the ratio of the arterial signals without noise. The ratio of the two arterial pulse-added absorbance signals and its value is used to find the SpO_2 saturation in a look-up table built into the Masimo SET® software. The values in the look-up table are based upon human blood studies against a laboratory CO-oximeter on healthy adult volunteer in induced hypoxia states.

Method of operation

The method of operation of the Model 2000 pulse oximeter is to turn on the monitor. An oximetery sensor is attached to a patient's finger and one end of a patient cable is connected to the sensor and the other end connected to the front panel connector of the Model 2000.

The monitor will begin continuously displaying the patient's pulse plethysmographic waveform, pulse rate and SpO_2 value. The practitioner can adjust the high and low alarm limits to their value, if required. The practitioner can then use the information that is continuously displayed on the monitor, and heard if an alarm limit is reached, to help assess the condition of the patient and as an aide in determining if any intervention is required by the practitioner.

Once the practitioner determines the patient no longer requires monitoring, the cable is disconnected from the sensor, the oximetry sensor is removed (and disposed of if it is a single use device), and the power to the monitor is turned off.

The Masimo SET® module with LNOP-Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

The Masimo SET® module with LNOP-Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. The variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Technological characteristics of the Model 2000 pulse oximeter compared to the Masimo SET® MS-1P pulse oximeter

The technological characteristics of the Model 2000 pulse oximeter and accessories and the Masimo SET® MS-1P pulse oximeter are the same or have similar technological characteristics in design, materials, and energy source.

The design of both devices is the same in that both devices are stand alone devices that monitor the oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by a SpO_2 sensor) for adult, pediatric and neonatal patients. The principles of operation and methods of operation for both devices is the same.

The materials used in both devices are similar. The electronics within the instruments are standard electronics parts (resistors, capacitors, integrated circuits, wiring, connectors, etc). The sensors and

cables for both devices are formed of thermoplastic materials, adhesives, wires, electrical contacts, light emitting diodes, and photodetectors.

The Model 2000 pulse oximeter and the Masimo SET® MS-1P pulse oximeter both operates from 85 - 265 VAC 47-63 Hz. Both can also operate under battery power.

Environmental testing

Applicable environmental testing i.e. electrical, mechanical and environmental were performed and all test passed.

Biocompatibility testing

All patient contact materials were tested as Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days) as defined ISO-10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Test. All patient contacting material passed.

Nonclinical test performed that support a determination of substantial equivalence

The Model 2000 pulse oximeter was subjected to bench testing using a simulator that determines the performance accuracy of the instruments against the simulator under the range of saturation and pulse rates that both devices specify.

Conclusions

The results of the environmental testing demonstrates that the Model 2000 pulse oximeter met the requirements of Reviewers Guidance for Premarket Submission - November 1993.

The results of the biocompatibility testing demonstrates the patient contacting material met the requirements of ISO-10993-1: 1992 Biological Evaluation of Medical Devices Part 1: Guidance on Selection of Test Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days).

The results of the bench testing demonstrates that the Model 2000 pulse oximeter meets its performance requirements.

The testing performed demonstrates that the Model 2000 pulse oximeter is safe, effective, and performs as well as the predicate device, the Masimo SET® MS-1P pulse oximeter, and therefore, it is substantially equivalent to the Masimo SET® pulse oximeter.

Signature

September 23, 1998
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1998

Mr. Dick Listro
Ivy Biomedical Systems, Inc.
11 Business Park Drive
Branford, CT 06405

Re: K982255
Model 2000 Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: September 23, 1998
Received: September 25, 1998

Dear Mr. Listro:

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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K982255

Device Name: Model 2000 Pulse Oximeter

Indications For Use:

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Contraindication For Use:

The Model 2000 Pulse Oximeter is contraindicated for use as a apnea monitor.

(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 Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use ✓ **or** **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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