K031465

OCT 1 0 2003

Dolphin Medical

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Dolphin Medical 2100 Pulse Oximeter and Accessories
4/16/03

Submitter Company
Dolphin Medical – FL
13801 McCormick Dr
Tampa, FL 33626

Contact: Jon Werner
Phone: 813-818-7488 x208
Fax: 813-818-7488

Sponsor Company
Dolphin Medical, Inc.
12525 Chadron Avenue
Hawthorne, CA 90250

Contact: Tammy Conway
Phone: 310-349-2308
Fax: 310-978-1816

Manufacturing Facility
Opto Sensors (M) Sdn. Bhd.
No. 6 Jalan Angkasa Mas 1
Tebrau Industrial Estate II
81100 Johor Bahru, Malaysia

Common, Classification & Proprietary Names

Common Name:	Oximeter
Classification Name:	Oximeter Class II – 21 CFR 870.2700 – 74 DQA
Proprietary Name:	Dolphin Medical Stand-Alone Pulse Oximeter, Model No. 2100 and Accessories.

Intended Use
The Dolphin Medical 2100 Pulse Oximeter is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor).

Predicate Device
The Dolphin Medical Pulse Oximeter and Accessories is substantially equivalent to the following currently marketed device(s):

- Dolphin Medical Stand-Alone Pulse Oximeter, Model No. 2100 and Accessories #K002036, #K012533, #K012626, #K020075, #K021959 and #K024235.

The Dolphin Medical Pulse Oximeter Model 2100 and Accessories is a portable stand-alone device, connecting cable, and oximetry sensor(s) to noninvasively calculate the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adult, pediatric and neonatal patients.

The monitor consists of a screen that displays the pulse plethysmographic waveform, the pulse rate, SpO_2 value, the high and low SpO_2 and pulse rate alarm limits, alarms, trends and status messages. It contains the electronic hardware and software that receives and calculates the signals from the LEDs within the sensor to determine the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate, and provide for the connection to the connecting cable.

The Dolphin Medical Pulse Oximeter Model 2100 is available in one configuration as a portable stand-alone oximeter that is 10 cm / 3.94 inches high, 27.5 cm / 10.83 inches wide, 25 cm / 9.84 inches deep and weighs about 4 kg / 8.8 lbs. The unit is powered either with a voltage input of 100-240 Vac, 50-60 Hz or with a sealed lead-acid battery with an operating time of approximately 4 hours based upon 2 Ampere hour battery (200mA OEM Module, 300mA System Module) and a charge time of about 4.5 hours to 80% capacity.

The extension cable connects between the monitor and oximetry sensor(s) and transfers LED drive power and the calibration drive to the oximetry sensor from the monitor and the monitor receives the detector signal from the oximetry sensor.

The extension cable is available in one configuration and is approximately 8 feet / 2.44m in length, and the sensor(s) are approximately 18 inches / 45.72 cm in length.

The sensor(s) measure 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.

The oximetry sensor is available in either a disposable or reusable configuration, and with one configuration for the extension cable (8 feet).

The Dolphin Medical Stand-Alone Pulse Oximeter, Model No. 2100 and Accessories have been designed to comply with the following standards:

1. CSA C22.2 No. 601.1
2. IEC 601-1, Part 1 and Amendments 1 and 2
3. IEC 601-1-1, Part 1
4. IEC 601-1-2, Part 1
5. ISO 9919: 1992
6. EN 865: 1997
7. FDA Guidance Document for Pulse Oximeters: 9/7/1992
8. ASTM 1415:1992, and Draft 10.1
9. UL2601-1: Second Edition, 1997
10. IEC 60068-2-6
11. IEC 60068-2-27
12. IEC 60068-2-64
13. ISTA Procedure 2A

The Dolphin Medical Stand-Alone Pulse Oximeter, Model No. 2100 and Accessories are identical to the Dolphin Medical Stand-Alone Pulse Oximeter Model No. 2100 and Accessories previously reviewed under #K024235 with only one exception. The software was updated in the Dolphin ONE OEM-601 Module, the component that functions as the oximetry engine. A review of the FDA guidance document "Deciding When to Submit a 510(k) for Change to an Existing Device," (January 10, 1997) was performed to determine if a 510(k) submission is necessary for the modified device. Based on the review of the product documentation and an evaluation of the 510(k) decision tree, it is our assessment that the product does not raise any new patient safety issues but does require a 510(k) review of the clinical data to establish safety and effectiveness for purposes of substantial equivalence. As a result, the clinical data and the internal software validation of the OEM-601 Module have been provided for your review.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Mr. Jon Werner
QA Manager
Dolphin Medical Incoporated
13801 McCormick Drive
Tampa, Fl 33626

Re: K031465
Trade/Device Name: Model 2100 Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 11, 2003
Received: September 12, 2003

Dear Mr. Werner:

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.

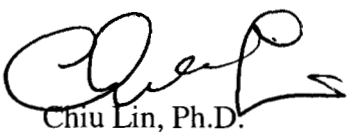
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

INDICATIONS FOR INTENDED USE FOR 2100 PULSE OXIMETER

510(k) Number (if known): K031465

Device Name: Dolphin Medical Stand-Alone Pulse Oximeter, Model No. 2100

May 2, 2003

Indications for Use:
The Dolphin Medical Stand-Alone Pulse Oximeter, Model No. 2100 and Accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor).

(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 Anesthesia, General Hospital, Infection Control, and Dental Devices (DAGID)

510(k) Number: K031465

Prescription Use ✓ OR over-the-counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number: K031465