K030952

MAY 19 2003

14. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Dolphin 2000™ Pulse Oximetry Sensor
3/14/02

Submitter (Consultant name and Address)

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Sponsor Company Name and Address and Contact Person

Dolphin Medical Inc.
12525 Chadron Avenue
Hawthorne, CA 90250

Paul Lee, Regulatory Affairs Specialist
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Manufacturing Facility Name and Address

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

Common, Classification & Proprietary Names

Common Name:	oximetry sensor
Classification Name:	oximeter
Proprietary Name:	Dolphin™ 2000 Oximetry Sensors

Predicate Devices

Sensor Name	Dolphin Model	Dolphin 2000 Predicate Model found in K012989 #	Nellcor Predicate found in K863784 & K991823
Nellcor Reusable Dolphin 2000 Oximetry Sensor	2010	2050	DS-100A
Nellcor Adult Disposable Dolphin 2000 Oximetry Sensor	2311	2351	D-25
Nellcor Pediatric Disposable Dolphin 2000 Oximetry Sensor	2312	2352	D-20
Nellcor Infant Disposable Dolphin 2000 Oximetry Sensor	2313	2353	I-20
Nellcor Neonatal Dolphin 2000 Oximetry Sensor	2314	2354	N-25
Adapter Cable	2421	2425	N/A

Device Description

The Dolphin 2000 Oximetry Sensors are fully compatible disposable and re-usable replacement sensors for use with Nellcor pulse oximeter monitors. They represent a design change to the Dolphin 2000 BCI Compatible Sensors.

The disposable Dolphin 2000 Oximetry Sensors are constructed in a similar manner to predicate devices. The emitter and detector diodes are embedded in a laminate of tapes that is connected to the cable assembly. The sensors have an adhesive bandage backing that allows the sensor to be applied to the patient by wrapping it around a finger or toe (measurement site). Four sizes of disposable Dolphin 2000 Oximetry Sensors are available, which are indicated for use for adult, pediatric, infant and neonatal application sites. The Dolphin 2000 disposable sensors are provided non-sterile for single patient use.

The re-usable Dolphin 2000 Finger Clip Oximetry Sensor is an adult-sized clothespin-style clip that is placed on the end of a finger. The finger clip sensor consists of the emitter and detector components mounted in opposing clip halves, maintained in mild compression by a spring hinge. The molded outer components house the optoelectric components within contoured pads that maintain contact with the patient's finger. Clear windows within these pads permit the optical energy to pass through the finger for the measurements. The Dolphin 2000 re-usable sensors are provided non-sterile.

Intended Use

The Dolphin 2000 Oximetry Sensors are indicated for use in continuous monitoring of arterial oxygen saturation and pulse rate. They are fully compatible replacement sensors intended for use with major brands of pulse oximeters.

Technological Characteristics Comparison

The Dolphin 2000 Oximetry Sensors are substantially equivalent in intended use, design, principles of operation, materials, and performance to commercially available oximetry sensors.

All of the Dolphin 2000 oximetry sensors and the predicate devices operate on the identical principles of non-invasive optical assessment of tissue oxygenation using emitters (LEDs) and detectors (photodiode).

The Dolphin 2000 oximetry sensors are designed, configured, and manufactured for full compatibility for use with the labeled, commercially-available oximetry monitors listed above. They are constructed of similar materials and components of equivalent specifications as used in the predicate devices.

The Dolphin 2000 oximetry sensors, like the predicate devices are available in both disposable and re-usable styles, labeled for use in adult, pediatric, infant and neonatal populations.

The labeled accuracy of the Dolphin 2000 sensors is equivalent to those of the predicate devices.

Performance Testing

- **Biocompatibility**

  Biocompatibility tests, appropriate for skin-contacting devices for prolonged exposure, were performed on the each of the device components used in the assembly of the Dolphin 2000™ pulse oximetry sensors by the respective component manufacturer. Test results demonstrated the materials to be non-toxic, non-irritant, and non-sensitizing.

- **Electrical Safety**

  The Dolphin 2000 Oximetry Sensors have been tested and found to comply with the applicable clauses of the following standards:

  - EN 60601-1 (1990) Medical electrical equipment - part 1: General requirements for safety
  - EN 60601-1-1 (1993) Medical electrical equipment - part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems
  - EN 60601-1-2 (1993) Medical electrical equipment - part 1: General requirements for safety - 2. Collateral standard: Electromagnetic compatibility - requirements and tests
  - ASTM F1415-92 Standard Specification for Pulse Oximeters

Clinical Testing

The sensors were validated in breathe-down protocols at the VA Hospital of Wisconsin – Milwaukee, (Dr. Phillip Clifford, MD.). Scientific accuracy was demonstrated by statistically comparing Dolphin 2000 SpO_2 values to functional SaO2 values. Volunteers participated in the breathe-down protocol at rest (i.e. no motion) while fully conscious at SaO2 values ranging from 70-100%. Data was analyzed to determine the ARMS for each probe. Clinical Validation for the Dolphin 2000 Reusable, Adult disposable, and Neonatal disposable probes resulted in an accuracy determination of less then 2.0% A_{RMS} in the range of 70-100% Sa02 for adults, pediatrics, and infants and less than 3% Arms in the range of 70-100 for Neonates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 9 2003

Mr. Bill Curnan
Regulatory Specialist
Dolphin Medical Incorporated
9433 S. Morning Glory Lane
Littleton, Colorado 80130

Re: K030952
Trade/Device Name: Nellcor Compatible Dolphin 2000 Oximetry Sensors (Models 2010, 2311, 2312, 2313, and 2314) and Adapter Cable
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 5, 2003
Received: May 6, 2003

Dear Mr. Curnan:

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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use (FDA Form)

510(k): K030952

Device: **DOLPHIN 2000 Oximetry Sensors**

Indications for Use:

The Dolphin 2000 Oximetry Sensors are indicated for use in continuous monitoring of arterial oxygen saturation and pulse rate.

prescription device ✓

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

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