MAR 2 0 2002

14. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K012989

Dolphin 2000™ Pulse Oximetry Sensor
3/14/02

Submitter (Consultant name and Address)

Bill Curnan
9433 S. Morning Glory Lane
Highlands Ranch, CO 80130

Phone: 720-939-6482
Fax: 786-551-8221

Sponsor Company Name and Address and Contact Person

Dolphin Medical Inc.
12525 Chadron Avenue
Hawthorne, CA 90250

Paul Lee, Regulatory Affairs Specialist
phone: (310) 349-2416
fax: (310) 644-1727

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	Aristo Model (Predicate Device)	Original 510(k)
BCI Reusable Dolphin 2000 Oximetry Sensor	2050	222	K960251
BCI Adult Disposable Dolphin 2000 Oximetry Sensor	2351	221-1	K960251
BCI Pediatric Disposable Dolphin 2000 Oximetry Sensor	2352	221-2	K960251
BCI Infant Disposable Dolphin 2000 Oximetry Sensor	2353	221-3	K960251
BCI Neonatal Dolphin 2000 Oximetry Sensor	2354	221-4	K960251

Device Description

The Dolphin 2000 Oximetry Sensors are fully compatible disposable and re-usable replacement sensors for use with BCI pulse oximeter monitors. They represent a redesign and updating of the Aristo Sensor Line.

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. Specifically, the Dolphin 2000 Oximetry Sensors are substantially equivalent to the Aristo oximetry sensors manufactured by Opto Sensors (M) Sdn. Bhd.

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.

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
- EN 865 (1997) Pulse Oximeters – Particular Requirements
- ASTM F1415-92 Standard Specification for Pulse Oximeters

Clinical Testing

.The sensors were validated in two breathe-down protocols, one at the University of California at San Francisco ('UCSF') Department of Anesthesiology (John W. Severinghaus, MD.), and a second 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. Sixteen 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, Neonatal disposable for BCI 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

MAR 2 0 2002

Mr. Bill Curnan
Dolphin Medical, Inc.
C/0 Curnan Consulting
9433 S. Morning Glory Lane
Highlands Ranch, CO 80130

Re: K012989
Dolphin 2000 Oximeter Sensors (Models 2050, 2351, 2352, 2353, and 2354)
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: DQA
Dated: February 20, 2002
Received: February 20, 2002

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.

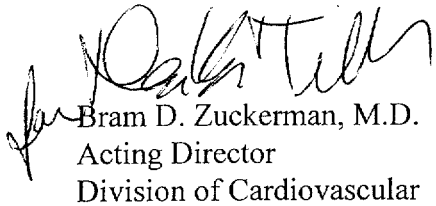
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B

Statement of Indications for Use (FDA Form)

510(k): K012989

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 Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012989