AUG 3 1 2004

K040380

14.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Dolphin ONE™ Pulse Oximetry Forehead Sensor
1/23/04

Submitter (Consultant Name and Address)
Jon Werner
14240 N 42nd St #205
Tampa, FL 33613

Phone: 813-431-1444
Fax: 501-646-5851

Sponsor Company Name and Address and Contact Person
Dolphin Medical, Inc.
12525 Chadron Avenue
Hawthorne, CA 90250

Tammy Conway, QA Manager
Phone: 310-349-2308
Fax: 310-978-1816

Manufacturing Facility Name and Address
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:	Oximetry Sensor
Classification Name:	Oximeter
Proprietary Name:	Dolphin ONE™ Oximetry Sensors

Predicate Devices

Sensor	Dolphin Model	Dolphin ONE Predicate Model found in K030629
Dolphin ONE Reusable Oximetry Forehead Sensor	420	320

Device Description
The Dolphin ONE Forehead Oximetry Sensor is a reusable sensor for use with approved Dolphin ONE pulse oximeter monitors.

The reusable forehead sensor is for use on the forehead and held in place with a disposable adhesive disc and headband. The emitter and detector are mounted in a sealed pouch (same materials as in the reusable Y sensor above) constructed in a flat cylindrical shape. The sensor is provided non-sterile.

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

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

All of the Dolphin ONE 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 ONE Oximetry Sensors are designed, configured, and manufactured for full compatibility for use with the labeled, commercially available oximetry monitors. They are constructed of similar materials and components of equivalent specifications as used in the predicate devices.

The labeled accuracy of the Dolphin ONE Sensors is equivalent to those of the predicate devices.

Performance Testing

- Biocompatibility
  The Dolphin ONE Model 420 Forehead Sensor utilizes the same sensor body, cable, and keyed connector materials as the Dolphin ONE Sensors approved in #K030629 and have been sold worldwide with no reports of biocompatibility issues. The material changes from the Model 320 Sensor have either been approved in other Dolphin Medical Sensor Models or have certifications to demonstrate the materials to be non-toxic, non-irritant, and non-sensitizing.
- Validation Testing
  The Dolphin ONE Oximetry Sensors have been tested and found to comply with environmental specifications, pulse rate specifications, and skin temperature requirements as per ASTM 1415.

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 ONE SpO2 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 ONE Forehead Sensor resulted in an accuracy determination of less than 2.0 ARMS in the range of 70-100% SaO2 for adults and pediatrics > 30 kg.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2004

Dolphin Medical, Incorporated
C/O Mr. Jon Werner
Regulatory Consultant
14240 N. 42nd Street
Tampa, Florida 33613

Re: K040380
Trade/Device Name: Dolphin Medical Dolphin ONE Adult Reusable Forehead Senor Model 420
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 20, 2004
Received: August 23, 2004

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.

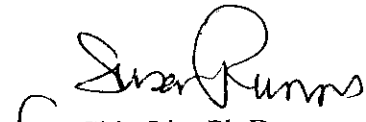
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known): K040380

Device Name: Dolphin Medical Dolphin ONE Adult Reusable Forehead Sensor Model 420

Indications For Use:

The Dolphin ONE Model 420 oximetry sensor is indicated for continuous noninvasive monitoring of arterial oxygen saturation and pulse rate.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040380