NOV 7 2002

K014218

November 6, 2002

Subject: Summary of Safety and Effectiveness Information for the Dolphin Medical Voyager Pulse Oximeter and Accessories
Proprietary: Dolphin Medical Voyager Pulse Oximeter and Accessories
Common: Oximeter
Classification: Oximeter Class II – 21 CFR 870.2700 – 74 DQA

The Pocket PC based Dolphin Medical Voyager Pulse Oximeter and Accessories, is fully functional handheld device to noninvasively calculate the functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate through a Compact Flash (CF) Card.

The Dolphin Medical Voyager 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.
- QRS Diagnostic Spiroxcard Diagnostic Spirometer and Pulse Oximeter #K001995.

The Voyager consists of a CF card, and a connecting cable and is sold with the Dolphin ONE reusable and disposable sensors and the Dolphin Voyager Software as accessories. The user is required to load the Dolphin Voyager Software on a Pocket PC. The Voyager is intended for battery use only using the internal Pocket PC battery. The oximeter must not be used when connected to any other device, or when placed in the recharging cradle provided by the Pocket PC manufacturer. The Dolphin Voyager software will disable the oximetry function and display a message "Unit Charging – Do Not Use" when external power is detected.

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

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 Dolphin Medical Voyager Pulse Oximeter and Accessories is substantially equivalent in design concepts, technologies and materials to the Dolphin Medical Dolphin Stand-Alone Pulse Oximeter. Formal testing has been performed for the device including Safety and Emissions, and performance validation which has been included in this submission.

The Dolphin Medical Voyager and Accessories were clinically validated in two breathe-down protocols at the VA Hospital of Wisconsin – Milwaukee (Dr. Philip Clifford, MD). Scientific accuracy was demonstrated by statistically comparing Dolphin ONE SpO_2 values to functional SaO_2 values. Fourteen volunteers participated in the breathe-down protocol at rest (i.e. no motion) while fully conscious at SaO_2 values ranging from 70-100%. Data was analyzed to determine the A_{RMS} for each probe. Clinical validation for the Adult Reusable and Adult Disposable resulted in an accuracy determination of less than 2.0% A_{RMS} for adults and pediatrics > 30 kg in the range of 70-100% SaO_2. The Neonatal Disposable resulted in an accuracy determination of less than 2.2% for pediatrics $\leq$ 30 kg and less than 3.5% for neonates in the range of 70-100% SaO_2.

The Dolphin Medical Voyager Pulse Oximeter and Accessories have been designed to comply with the following standards:

1. EN60601-1 Medical Electrical Equipment; Part 1: General requirements for safety (includes Amendments 1 and 2)
2. EN 60601-1-1: Medical Electrical Equipment; Part 1: General requirements for safety – 1. Collateral standard: Safety requirements for medical electrical systems.
3. UL 2601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety
4. EN 865 Pulse Oximeter - Particular requirements
5. CSA C22.2 #601 Medical Electrical Equipment Part 1: General Requirements for Safety
6. EN 60601-1-2: Medical Electrical Equipment; Part 1: General requirements for safety - 2.
    a. Collateral standard: Electromagnetic compatibility - Requirements and tests
7. ISO 9919: Pulse Oximeters for medical use – Requirements
8. IEC 60068-2-6: Environmental testing - Part 2: Tests - Test Fc: Vibration (sinusoidal)
9. IEC 60068-2-27: Environmental testing. Part 2: Tests. Test Ea and guidance: Shock
10. IEC 60068-2-64: Environmental testing - Part 2: Test methods - Test Fh: Vibration,
    a. broad-band random (digital control) and guidance
11. ISTA Procedure 2A: Integrity-Plus Test Procedure, Performance Test for Individual
        i. Package-Product 150lb (68.2kg) or Less
12. MIL-STD-810E, 501.3 Operating and Storage High Temperature
13. MIL-STD-810E, 502.3 Operating and Storage Low Temperature
14. MIL-STD-810E, 503.3 Temperature Shock
15. MIL-STD-810E, 507.3 Procedure III: Humidity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

Mr. Jon Werner
Quality Assurance Manager
Dolphin Medical, Incorporated
OSI Medical, Incorporated
13801 McCormick Drive
Tampa, Florida 33626

Re: K014218
Trade/Device Name: Dolphin Medical Voyager Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 10, 2002
Received: August 12, 2002

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.

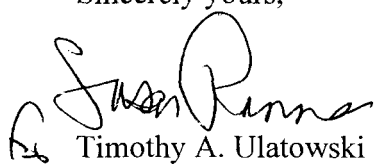
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification
Intended Use and Indications for Use Statement

510(k) Number (if known): ____K014218_____

Device Name: Dolphin Medical Voyager Pulse Oximeter

November 6, 2002

Intended Use:
The Dolphin Medical Voyager Pulse Oximeter and Accessories are indicated for the non-continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an oximetry sensor). The oximeter is indicated for use with a Pocket PC (with Windows CE Operating System).

(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: K 014218

Prescription Use X OR over-the-counter Use_____
(Per 21 CFR 801.109)