K011518

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EXECUTIVE SUMMARY

VitalSat Series Pulse Oximeter Sensor

510(k) Summary

Submitted By: Beta BioMed Services, Inc.
3301 Century Drive, Suite E
Rowlett, TX 75088
800-315-7551

Contact: Mike A. Scanlan
Director of Research and Development

Trade Name: VitalSat Series Pulse Oximeter Sensors

Common/Classification Name: Oximeter (74DQA)

Substantially Equivalent Devices: Ohmeda Biox 3700 K850494
Ohmeda Biox 3740 K872772
Ohmeda Biox 3760 K874104

DEVICE DESCRIPTION

The VitalSat Series Pulse Oximeter Sensors are reusable clip on sensors designed to function with the compatible Original Equipment Manufacturer (OEM) Pulse Oximeter Sensor. The VitalSat Series Pulse Oximeter Sensors use two Light Emitting Diodes (LED's) and a photo detector contained in a molded plastic housing, and is Latex free. The sensor cable terminates into an OEM compatible connector. The VitalSat Series Pulse Oximeter Sensors transfers power from the monitor to the LED's, and transfers the detected signal back to the monitor to determine the functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate.

INTENDED USE

The VitalSat Series Pulse Oximeter Sensors are intended for continuous non-invasive monitoring of l oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult and pediatric patients in hospitals and hospital like facilities. The VitalSat Series Pulse Oximeter Sensors are a prescription devices intended to be used by health care professionals only. The VitalSat Pulse Oximeter Sensors are compatible with the Ohmeda Biox 3740 or equivalent Pulse Oximeter.

CONTRAINDICATIONS FOR USE

TheVitalSat Series Pulse Oximeter Sensors are contraindicated for use for prolonged periods of use. It is not intended for use for long term monitoring. The sensor must be removed and repositioned every four hours, and if indicated by circulatory condition or skin integrity, and reapplied to a different monitoring site.

TECHNOLOGICAL CHARACTERISTICS

The VitalSat Series Pulse Oximeter Sensors measure oxygen saturation and pulse rate using equivalent technology to the currently marketed predicate devices.

The safety and effectiveness of the VitalSat Series Pulse Oximeter Sensors has been demonstrated by design and testing. Electrical safety was tested by Beta BioMed Services Inc. in accordance with applicable requirements of UL 2601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety. Test results demonstrated that all applicable requirements have been met.

The accuracy and performance of the VitalSat Series Pulse Oximeter Sensors has been demonstrated through both bench and clinical testing. Bench testing was conducted utilizing a patient simulator. Test results demonstrate that the accuracy of the pulse and oxygen saturation levels reported by the VitalSat Series Pulse Oximeter Sensors in equivalent to the currently marketed predicate devices.

The results of a Co-Oximeter Correlation Study indicate that the VitalSat Series Pulse Oximeter Sensors are equivalent to the currently marketed predicate devices and meet the stated accuracy specifications.

BIOCOMPATIBILITY

The VitalSat Series Pulse Oximeter Sensors were tested and found to meet the requirements of the International Organization for Standardization, ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Test for Cytoxicity, *In Vitro* Methods, Reference Number ISO 10993-5:1992(E), and ISO 10993-10 Tests for Irritation and Sensitization, Reference Number ISO 10993-10:1995(E).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2002

Beta BioMed Services, Incorporated
C/O Mr. E. J. Smith
Smith Associates
P.O. Box 4341
Crofton, Maryland 21114

Re: K011518
Trade/Device Name: VitalSat Series Pulse Oximeter Sensor
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: October 9, 2002
Received: October 9, 2002

Dear Mr. Smith:

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) Number (K011518):

Device Name: Pulse Oximeter Sensor

Classification Panel: DQA

Indications for Use:

The VitalSat 1017 Pulse Oximeter Sensors are intended to be used for the continuous non-invasive monitoring of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult and pediatric patients in hospitals and hospital like facilities. The VitalSat Series Pulse Oximeter Sensors prescription devices intended to be used by health care professionals only. The VitalSat 1017 Pulse Oximeter Sensors have been validated on the Ohmeda Biox 3740 Pulse Oximeter.

Warning: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

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

510(k) Number: K011518