K981655

DEC - 3 1999

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Spacelabs Medical Disposable SpO2 Sensors

1. Submitter's Name/ Contact Person: Irene Jaworski
   Director of Regulatory Affairs and Quality
   Company: Spacelabs Medical Inc.
   15220 N.E. 40th Street
   Redmond, WA 98073
   Telephone: (425) 882-3913
   Facsimile: (425) 867-3550

2. Name of Device: Spacelabs Medical Disposable SpO2 Sensor

   Classification: Oximeter
   74DQA; 21 CFR 870.2700
   Class II

3. Predicate Device(s): We consider the Spacelabs Medical family of Disposable SpO2 Sensors to be substantially equivalent to features offered by currently-marketed devices with identical intended uses. Specifically, these sensors are substantially equivalent to disposable sensors marketed by Nellcor Puritan Bennett (510(k) reference K915699), Novamterix (K893643) and Ohmeda (K962127) for monitoring pulse oxygen saturation.

4. Device Description: As an accessory to a pulse oximeter monitoring module in a Spacelabs Medical Patient Care Information System (PCIS), a Spacelabs Medical Disposable SpO2 sensor provides the means to noninvasively acquire SpO2 signals from the patient's fingertip or for the continuous monitoring of pulse saturation signals.

   The SpO2 sensor converts optical signals into electrical signals from common monitoring sites. The acquired signals are transferred via an adapter cable to a pulse oximeter monitor for subsequent display, review, and editing by the care provider.

   Sensors are available for specific monitoring sites, including the fingertip and foot, and are sized to meet various adult, pediatric and infant patient needs.

5. Intended Use:

The Spacelabs Medical Disposable SpO2 Sensor is intended as a disposable, single-patient use accessory to a PCIS system for the acquisition of oxygen saturation signals from adult, pediatric and infant populations. The sensors may be used in a clinical environment where noninvasive monitoring of oxygen saturation for the detection of desaturation due to abnormal pulmonary/circulatory functions is required. Acquired data communicated via a sensor adapter cable to an information network for display recording, editing and analysis.

Spacelabs Medical intends to sell the Disposable SpO2 Sensor in two basic configurations: (1) sterile and (2) non-sterile.

6. Comparison of Technological Characteristics

We consider the family of Spacelabs Medical Disposable SpO2 Sensors to be substantially equivalent to sensors currently marketed by Nellcor Puritan Bennett, Novamterix, and Ohmeda.

The design, materials, methods of skin application, cable connections to a display unit, and SpO2 signal acquisition technology are similar to the predicate sensors. Sensors from all these manufacturers provide the means for interfacing with a patient to acquire SpO2 physiologic data and forwarding it via a sensor cable interface to a monitor for alarm generation and display of numeric values and waveforms on a bedside or central monitoring system.

The only significant differences between the Spacelabs Medical and the predicate devices are in the design of the photo-detector sensor and the selection of the bandage material in the Spacelabs Medical sensors. Spacelabs has selected a smaller photo-detector to reduce signal saturation on patients with translucent skin. The photo-detector on the sensor is slightly raised when positioned on the patient to improve the quality of the signal. The adult and pediatric Spacelabs Medical sensors also incorporate a clear bandage material to facilitate the visual inspection of the sensor site when attached to the patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Irene Jaworski
Spacelabs Medical, Inc.
15220 N.E. 40th Street
P.O. Box 97013
Redmond, WA 98073-9713

Re: K981655
Spacelabs Medical Disposable Pulse Oximeter (SpO2) Sensors
Models 703-0002-00, 703-0003-00 and 703-0004-00
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: October 22, 1999
Received: November 1, 1999

Dear Ms. Irene Jaworski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Joanne B Witten for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K981655

Device Name: Spacelabs Medical Disposable SpO2 Sensors

Indications for Use:

Physiological purpose.
An accessory to an SpO2 monitoring system for use in noninvasive, continuous monitoring of oxygen saturation for the detection of desaturation due to abnormal pulmonary/circulatory function in adult, pediatric or infant population by the standard photoelectric pulse of oximetric technique.

Parts of body applied to:
Sensors are available for common monitoring sites, including the fingertip and foot.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K981655