FEB 18 2011

II. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Garrett Ahlborg
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Date Prepared: September 3, 2010

Trade Name: Reprocessed Pulse Oximeter Sensors

Classification Name: Oximeter, Reprocessed

Classification Number: Class II, 21 CFR 870.2700

Product Code: NLF

Predicate Devices:	The SterilMed reprocessed pulse oximeter sensors are substantially equivalent to the Masimo LNCS® pulse oximeter sensors (K041815, K051212, & K060143).
Device Description:	SterilMed's reprocessed pulse oximeter sensors consist of a sensor, integrated sensor cable, and a sensor plug which connects to the Pulse Oximeter. These devices feature a sensor that uses an optical means to determine the light absorption of functional arterial hemoglobin. The sensor contains three optical components: two light emitting diodes (LED's) that serve as light sources, and one photodiode, that acts as a light receiver. The oximeter sensor is positioned so that the LED's and photodiode oppose one another across the tissue. The sensor is connected via cable to a pulse oximeter, which provides continuous noninvasive, self-calibrated measurements of both oxygen saturation of functional hemoglobin and pulse rate. Note: Only the pulse oximeter sensor is the subject of this submission, the oximeter and any other related equipment are not included in the scope of this submission.
Intended Use:	The reprocessed pulse oximeter sensors are indicated for use for continuous noninvasive arterial oxygen saturation (SpO_2) and pulse rate monitoring.
Functional and Safety Testing:	Representative samples of reprocessed pulse oximeter sensors were tested to demonstrate appropriate functional characteristics by utilizing the necessary bench testing and *in vivo* clinical validations. Process validation testing was performed to validate the sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Summary of Non-clinical Tests Conducted:	Specific non-clinical tests included: sterilization validation (ISO 11135, USP <71>), ethylene oxide residual testing (ISO 10993-7), bioburden testing, packaging validation (ASTM D4169, ASTM F88) and shelf life validation (ASTM 1980-99). In addition, validation of functional performance (bench testing) was performed and included the following tests: S_pO_2 and pulse rate accuracy (normal and low perfusion) using a simulated tester, S_pO_2 and pulse rate accuracy under varying environmental conditions, and physical tests to verify structural integrity after reprocessing.
Summary of Clinical Tests Conducted:	*In vivo* clinical studies were conducted on both adult volunteers and neonatal subjects to demonstrate S_pO_2 accuracy of the reprocessed sensors.
Conclusion:	The reprocessed pulse oximeter sensors are substantially equivalent to the Masimo pulse oximeter sensors. This conclusion is based upon the devices' similarities in functional performance and design (principles of operation), materials, clinical validation results, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Garrett Ahlborg
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FEB 18 2011

Re: K102560
Trade/Device Name: Reprocessed Pulse Oximeter Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: February 14, 2011
Received: February 15, 2011

Dear Mr. Ahlborg:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
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):

Device Name: Reprocessed Pulse Oximeter Sensors

Indications for Use:

The reprocessed pulse oximeter sensors are indicated for use for continuous noninvasive arterial oxygen saturation (SpO_2) and pulse rate monitoring.

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: K102568