DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

Dr. Bruce Lester
Vice President of Research and Development
SterilMed, Incorporated
11400 73Rd. Avenue North
Minneapolis, Minnesota 55369

Re: K012677 - Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: August 13, 2001
Received: August 14, 2001

Dear Dr. Lester:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on March 28, 2003. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are 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 these devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA) they 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 devices 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 devices comply 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 applicable 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.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. 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

Trade/Device Names

SterilMed Reprocessed Nellcor Pulse Oximeter Oxisensor II Sensor N-25
SterilMed Reprocessed Nellcor Pulse Oximeter Oxisensor II Sensor N-25LF

Indications for use Page

510(k) Number K012677

Device Name: Reprocessed Pulse Oximeter Sensors

Indications for Use:

Reprocessed Pulse Oximeter Sensors are intended for use when continuous external monitoring of arterial oxygen saturation and pulse rate are required.

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ PRESCRIPTION

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

510(k) Number: K012677

K012677

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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Patrick Fleischhacker
Submitted by SterilMed, Inc.
11400 73rd Avenue North
Minneapolis, MN 55369
Ph: 888-856-4870
Fax: 763-488-3350

Date Prepared: August 13, 2001

Trade Name: SterilMed Reprocessed Pulse Oximeter Sensors

Classification Name: and Number: Class II, 21 CFR 870.2700

Product Code: DQA

Predicate Device(s): The reprocessed pulse oximeter sensors are substantially equivalent to the Nellcor Oxisensors™, which are compatible with the Nellcor N-200 pulse oximeter (K863784).

Device Description: The reprocessed pulse oximeter sensor is an electro-optical 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 non-invasive, self-calibrated measurements of both oxygen saturation of functional hemoglobin and pulse rate. Please note that this submission only pertains to the sensor. It does not pertain to the pulse oximeter or connecting cable.

Intended Use: Reprocessed pulse oximeter sensors are used when continuous external monitoring of arterial oxygen saturation and pulse rate is required.

Functional and Safety Testing:

Representative samples of reprocessed sensors underwent bench testing and a clinical study to verify functional characteristics which are substantially equivalent to the predicate devices'. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:

The pulse oximeter sensors reprocessed by SterilMed are substantially equivalent the Nellcor Oxisensors™ which are compatible with the Nellcor N-200 pulse oximeter. This conclusion is based upon the fact that the reprocessed sensors are substantially equivalent to their predicate devices in terms of functional design, materials, indications for use, and methods of construction.