K041127

Appendix F

510(k) Summary

Submitter:	SterilMed, Inc. 11400 73rd Ave. N Minneapolis, MN 55369 ERN: 2134070
Contact Person:	Dr. Bruce Lester VP Research and Develpoment SterilMed, Inc. 11400 73rd Avenue North Minneapolis, MN 55369 Phone: (888) 856-4870 Fax: (763) 488-3350
Date Prepared:	April 26, 2004
Trade Name:	Reprocessed Pulse Oximeter Sensors
Classification Name and Number:	21 CFR 870.2700
Product Code:	NLF
Predicate Device Name and 510(k) Number	Reprocessed Pulse Oximeter Sensors K012677
Device Description:	DEVICE DESCRIPTION The subject devices are reprocessed pulse oximeter sensors model numbers Max-A and Max-N Pulse Oximeter Sensors originally manufactured by Nellcor. 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.
Statement of Technological Comparison	The subject reprocessed Pulse Oximeter Sensors have the following similarities to the Reprocessed Pulse Oximeter Sensor which previously received 510(k) clearance: • The same indicated use; • The same operating principle; • The same basic design; • The same technical characteristics; • The same clinical performance characteristics; • The same manufacturing environment; • The same sterilization process; and • The same packaging configurations. In summary, the subject device described in this submission is, in the opinion of SterilMed, substantially equivalent to the predicate device.
Conclusion:	The subject reprocessed pulse oximeter sensors are substantially equivalent to the predicate reprocessed pulse oximeter sensors. This conclusion is based upon the fact that this device is substantially equivalent to the predicate device in terms of functional design, indications for use, principles of operation and test performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2004

Dr. Bruce Lester
Vice President Research & Development
SterilMed, Incorporated
11400 73rd Avenue, North
Minneapolis, Minnesota 55369

Re: K041127
Trade/Device Name: Modification To: Reprocessed Pulse Oximeter Sensors
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: July 27, 2004
Received: July 29, 2004

Dear Dr. Lester:

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.

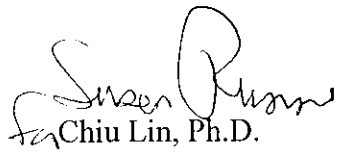
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-4613. 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,



for 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

Appendix B

Indications for Use Statement

510(k) Number (if known) TBD

Device Name Reprocessed Pulse Oximeter Sensors

Indications for Use Reprocessed Pulse Oximeter Sensors are used when continuous external monitoring of arterial oxygen saturation and pulse rate is required.

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)

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

510(k) Number: K041127