K083060

II. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person: Dennis Toussaint
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Maple Grove, MN 55369
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JAN - 9 2009

Date Prepared: October 10, 2008

Trade Name: Reprocessed Harmonic Scalpel

Classification Name: Scalpel, Ultrasonic, Reprocessed

Classification Number: Unclassified

Product Code: NLQ

Predicate Devices:	The reprocessed harmonic scalpels are substantially equivalent to Ethicon Harmonic WAVE™ harmonic scalpels.
Device Description:	SterilMed reprocessed harmonic scalpels are used in combination with a hand piece, generator and torque wrench and are intended to be used in soft tissue surgery for simultaneous cutting and coagulation of vessels and tissue. The instrument has a scissor handle with hand control capabilities consisting of MIN and MAX buttons. The handle housing has an integrated mechanism for limiting the force that can be applied when closing the distal mechanism. The instrument has an 18 cm shaft length, 8.5 mm shaft diameter, active blade length of 18 mm, and utilizes a straight blade and clamp arm. Note: Only the harmonic scalpel is the subject of this submission, the reusable hand piece, generator, and any other related equipment are not included in the scope of this submission.
Intended Use:	The reprocessed harmonic scalpels are indicated to be used for cutting of soft tissue and providing hemostasis when control of bleeding and minimal thermal injury is desired. The instrument can be used as an adjunct to, or a substitute for, electrosurgery, lasers, and steel scalpels in abdominal, pediatric, gynecologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures.
Functional and Safety Testing:	Representative samples of reprocessed harmonic scalpels were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Conclusion:	The reprocessed harmonic scalpels are substantially equivalent to Ethicon Harmonic WAVE™ harmonic scalpels. This conclusion is based upon the devices' similarities in functional design (principle of operation), materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SterilMed, Inc.
% Mr. Dennis Toussaint
Director of Regulatory Affairs
11400 73rd Avenue North
Maple Grove, Minnesota 55369

JAN - 9 2009

Re: K083060
Trade/Device Name: Reprocessed Harmonic Scalpels
Regulatory Class: Unclassified
Product Code: NLQ, LFL
Dated: October 10, 2008
Received: October 14, 2008

Dear Mr. Toussaint:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083060

Device Name: Reprocessed Harmonic Scalpels

Indications for Use:
The reprocessed harmonic scalpels are indicated to be used for cutting of soft tissue and providing hemostasis when control of bleeding and minimal thermal injury is desired.

The instrument can be used as an adjunct to or a substitute for electrosurgery, lasers, and steel scalpels in abdominal, pediatric, gynecologic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures.

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 General, Restorative,
and Neurological Devices

510(k) Number K083060

Devices included in this Premarket Notification Submission – 510(k) K083060

Manufacturer	Model #
Ethicon	WAVE18S