II. SUMMARY AND CERTIFICATION

A. 510(k) Summary

K132566

JUN 14 2014

Submitter: Sterilmed, Inc.

Contact Person: Jason Skramsted
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Date Prepared: 14 August 2013

Trade Name: Reprocessed Harmonic Shears

Regulation Name: Scalpel, Ultrasonic, Reprocessed

Device Classification: Unclassified

Product Code: NLQ

Predicate Devices:	The reprocessed harmonic shears are substantially equivalent to the Ethicon Harmonic Shears (K121550, K120729 and K060245).
Device Description:	The harmonic shears are used in combination with a handpiece, generator and torque wrench and are intended to be used for cutting and coagulation of soft tissue during laparoscopic and open procedures. The instruments allow the surgeon to grasp, coagulate and cut soft tissue with one instrument. The instruments allow for the coagulation of vessels up to and including 5 mm in diameter. The instruments are hand-actuated with a shaft and distal tip that can be rotated 360°. The ultrasonic energy is delivered by hand activation or with an optional generator foot switch.
Intended Use:	The reprocessed harmonic shears are intended to be used for cutting soft tissue and when control of bleeding and minimal thermal injury is desired. The instruments can be used as an adjunct to or a substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space) and other open and endoscopic procedures.
Technological Characteristics:	The reprocessed harmonic shears are identical to the predicate devices in design, materials of construction, and intended use. There are no changes to the clinical applications, patient population, performance specifications, or method of operation.
Functional and Safety Testing:	Representative samples of reprocessed harmonic shears 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.
Summary of Non-clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), biocompatibility testing (ISO 10993), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D 4169, ASTM F 88, ASTM F 2096), and shelf life validation (ASTM 1980). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, fatigue testing, and function testing. Performance testing shows the reprocessed harmonic shears to perform as originally intended.
Conclusion:	Sterilmed concludes that the reprocessed harmonic shears are safe, effective, and substantially equivalent to the predicate devices, Ethicon Harmonic Shears (K121550, K120729, and K060245), as described in this premarket notification submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 14, 2014

SterilMed
% Mr. Jason Skramsted
Regulatory Affairs Specialist
11400 73rd Avenue, North
Maple Grove, Minnesota 55369

Re: K132566
Trade/Device Name: Reprocessed Harmonic Shears (See enclosed list)
Regulatory Class: Unclassified
Product Code: NLQ
Dated: May 20, 2014
Received: May 21, 2014

Dear Mr. Skramsted:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Model Number	Device Name	Shaft Diameter	Shaft Length
HAR23M	Reprocessed Harmonic Shears	5 mm	23 cm
HAR36M	Reprocessed Harmonic Shears	5 mm	36 cm
ACE23E	Reprocessed Harmonic Shears	5 mm	23 cm
ACE36E	Reprocessed Harmonic Shears	5 mm	36 cm
N/A	Reprocessed Torque Wrench	N/A	N/A

Indications for Use

510(k) Number (if known): K132566

Device Name: Reprocessed Harmonic Shears

Indications for Use:

The reprocessed harmonic shears are intended to be used for cutting soft tissue and when control of bleeding and minimal thermal injury is desired. The instruments can be used as an adjunct to or a substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, 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)

Joshua C. Nipper -S