DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 20, 2016

Sterilmed, Inc.
Ms. Neelu Gibson
Senior Director, Regulatory Affairs
5010 Cheshire Parkway, Suite 2
Plymouth, Minnesota 55446

Re: K161086
Trade/Device Name: Reprocessed Harmonic Shears with Adaptive Tissue Technology (36 cm), Reprocessed Harmonic Shears with Adaptive Tissue Technology (23cm)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: August 19, 2016
Received: August 22, 2016

Dear Ms. Gibson:

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 Part 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 Parts 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" (21 CFR 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,

Christopher J. Ronk -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161086

Device Name
Reprocessed Harmonic Shears with Adaptive Tissue Technology (36 cm), Reprocessed Harmonic Shears with Adaptive Tissue Technology (23 cm)

Indications for Use *(Describe)*

The Reprocessed Harmonic Shears with Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K161086 Device Name and Model Numbers

Device Name	Model Number
Reprocessed Harmonic ACE®+ Shears, 5 mm Diameter, 23cm Length, With Adaptive Tissue Technology	HAR23R
Reprocessed Harmonic ACE®+ Shears, 5 mm Diameter, 36cm Length, With Adaptive Tissue Technology	HAR36R

K161086

510(k) SUMMARY

Submitter and Manufacturer:	Sterilmed, Inc. 5010 Cheshire Parkway N, Suite 2 Plymouth, MN 55446 www.sterilmed.com
Official Correspondent:	Neelu Gibson Sr. Director, Regulatory Affairs (RAC) Sterilmed, Inc. Tel: 908-705-3160 Fax: 763-488- 4576 Email: ngibson9@its.jnj.com
Date of Submission:	15 March 2016
Trade Name:	Reprocessed Harmonic Shears with Adaptive Tissue Technology (23 cm), Reprocessed Harmonic Shears with Adaptive Tissue Technology (36 cm)
Common Name:	Reprocessed Harmonic Shears with Adaptive Tissue Technology
510(k) Number:	K161086
Device Classification:	**Name:** Electrosurgical cutting and coagulation device and accessories. **Regulation:** 21CFR 878-4400 **Pro Code:** NUJ **Class:** Class II
Predicate Device:	Harmonic ACE Shears + Adaptive Tissue Technology (K121550).
Device Description:	The Reprocessed Harmonic Shears with Adaptive Tissue Technology are used for coagulation and mechanical transection of soft tissue during laparoscopic and open procedures. The devices allow the surgeon to grasp, coagulate and transect soft tissue with a single instrument. The devices are hand-actuated with shaft and tissue effector that can be rotated. The energy delivery can be activated with hand activation or with an optional generator foot switch. The device includes a torque wrench as an accessory piece (the torque wrench is designed to ensure that the hand piece is properly secured to the device.

Indications for Use:	The Reprocessed Harmonic Shears with Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or 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 with Adaptive Tissue Technology have the same technological and performance characteristics as the predicate devices, K121550. The reprocessed Harmonic Shears with Adaptive Tissue Technology incorporate an ergonomic handle and tapered blade geometry. Similar to the predicate models, each of these reprocessed devices includes an EEPROM memory chip that stores device identification, usage tracking, and operating parameters for use by the Ethicon Endo-Surgery, Inc. Generator 11 generator that provides power for the devices. Adaptive Tissue Technology refers to the power output algorithm that is utilized by the devices. During use, the Adaptive Tissue Technology algorithm parameters stored on the device EEPROM are read by the generator and used to reduce the power (current) to the instrument and provide a secondary, higher pitched generator activation tone when there is little or no tissue between the instrument blade and tissue pads. To do this the generator monitors the thermal condition of the blade during device activation.
Functional and Safety Testing:	Representative samples of reprocessed devices 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. Where appropriate prior validation testing of previously cleared Reprocessed Harmonic Shears (K132566) was utilized for the same reprocessing procedures, equipment, and sterilization processing. The Reprocessed Harmonic Shears with Adaptive Tissue Technology are reprocessed no more than one (1) time. The torque wrench accessories are reprocessed no more than five (5) times. Each device and accessory is marked and tracked through the reprocessing cycle. After the device or torque wrench has reached the maximum number of reprocessing cycles, one and five, respectively, it is rejected from further reprocessing.

Summary of Non-Clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization verification, ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D4169, ASTM F88, ASTM F2096), and shelf-life validation (ASTM 1980-07). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, and fatigue testing. Testing performed: • Electrical Safety • Device Functionality • Vessel Seal Burst (Static and Burst Pressure) • Vessel Seal Thermal Spread • Drop • Fluid Ingress • Pad Retention • Pad Failure • Clamp Force Performance testing shows the reprocessed Harmonic Shears with Adaptive Tissue Technology to perform as originally intended. In addition, the device was tested for biocompatibility per ISO 10993-1 for short duration contact with blood (<24 hours). Biocompatibility testing included: • Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity • Acute Systemic Toxicity • Hemocompatability • Chemical Pyrogens • Hemolysis • Immune Response
Conclusion:	Sterilmed conducted performance testing (described above) for the Reprocessed Harmonic Shears with Adaptive Tissue Technology (23 cm and 36 cm) against the OEM predicate devices, Harmonic ACE Shears + Adaptive Tissue Technology, Models HAR23 and HAR36 (K121550). Results demonstrated substantial equivalence to the predicate devices with respect to safety and effectiveness. Sterilmed therefore concludes that the Reprocessed Harmonic Shears with Adaptive Tissue Technology (23 cm, 36 cm) are safe, effective, and substantially equivalent to the predicate devices, Harmonic ACE Shears + Adaptive Tissue Technology, Models HAR23 and HAR36 (K121550)