August 15, 2019

SterilMed, Inc.
Jan Flegeau
Associate Director, Regulatory Affairs
5010 Cheshire Parkway N, Suite 2
Plymouth, Minnesota 55446

Re: K190610
Trade/Device Name: Reprocessed HARMONIC FOCUS Shears + Adaptive Tissue Technology
Regulatory Class: Unclassified
Product Code: NLQ
Dated: March 7, 2019
Received: March 11, 2019

Dear Jan Flegeau:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Reprocessed Single-Use Device Models Subject to Clearance:

OEM Model Number	Device Name/Description	Original Manufacturer	Reprocessed Model Number
HAR9F	Harmonic FOCUS Shears + Adaptive Tissue Technology	Ethicon	HAR9FR

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190610

Device Name
Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology

Indications for Use *(Describe)*
The Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Reprocessed Single-Use Device Models Subject to Clearance:

OEM Model Number	Device Name/Description	Original Manufacturer	Reprocessed Model Number
HAR9F	Harmonic FOCUS Shears + Adaptive Tissue Technology	Ethicon	HAR9FR

510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Date Prepared:	August 2, 2019
Submitter and Manufacturer:	Sterilmed, Inc. 5010 Cheshire Parkway N, Suite 2 Plymouth, MN 55446 www.sterilmed.com
Manufacturing Facility Address:	11400 73rd Avenue North Maple Grove MN 55369
Official Correspondent:	Jan Flegeau Associate Director, Regulatory Affairs SterilMed, Inc. Tel: 786-575-5903 Email: jflegeau@its.jnj.com
Trade Name:	Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology
Regulation Name:	Scalpel, Ultrasonic, Reprocessed
Device Classification:	Unclassified
Product Code	NLQ
Predicate Device:	HARMONIC FOCUS® Shears + Adaptive Tissue Technology (Ethicon K133314)
Device Description:	The Reprocessed Harmonic FOCUS Shears + Adaptive Tissue Technology is a sterile, single-patient use surgical instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument's working length is 9 cm in length with a 16 mm active blade length. The instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.
Model Numbers	HAR9FR
Indications For Use:	The Reprocessed Harmonic FOCUS Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic. exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Technological Characteristics:	The Reprocessed Harmonic FOCUS Shears + Adaptive Tissue Technology use an EEPROM memory chip that stores device identification, usage tracking, and operating parameters for use by the Generator G 11 that provides power for the Harmonic FOCUS Shears + Adaptive Tissue Technology. 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 as Adaptive Tissue Technology regulates the delivery of energy. To do this the generator monitors the thermal condition of the blade during device activation.
Functional and Safety Testing:	Reprocessed devices were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate cleaning and sterilization as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced. The Reprocessed Harmonic FOCUS Shears + Adaptive Tissue Technology, are reprocessed no more than one (1) time. The torque wrench accessories are reprocessed no more than two (2) times. Each device and accessory are marked and tracked through the reprocessing cycle. After the device or torque wrench has reached the maximum number of reprocessing cycles, one and two, 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. Performance testing conducted: • Grasping Force • Artery Seal Burst and Tissue Adhesion • Vein Seal Burst and Tissue Adhesion • Electrical and Thermal Safety IEC 60601 • Tissue (Jaw) Pad Life • Tissue (Jaw) Pad Removal Force • Thermal Spread and Transection Time Performance testing shows the Harmonic FOCUS Shears + Adaptive Tissue Technology performs as originally intended.

	In addition, the device was tested for biocompatibility per ISO 10993-1 for external communicating device, in contact with tissue/bone/dentin and the duration of contact is limited exposure (<24 hours). Biocompatibility testing included: • Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity • Acute Systemic Toxicity • Pyrogenicity
Conclusion:	Sterilmed conducted performance testing for the Reprocessed Harmonic FOCUS Shears + Adaptive Tissue Technology against the OEM predicate device, Ethicon Harmonic FOCUS Shears + Adaptive Tissue Technology (K133314). Results demonstrated substantial equivalence to the predicate devices with respect to safety and effectiveness. Sterilmed therefore concludes that the Reprocessed Harmonic FOCUS Shears + Adaptive Tissue Technology is safe, effective, and substantially equivalent to the predicate device, Ethicon Harmonic FOCUS Shears + Adaptive Tissue Technology.

Model Number included in submission K190610:

MODEL	**DESCRIPTION**
HAR9FR	Reprocessed HARMONIC FOCUS® Shears + Adaptive Tissue Technology