DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 23, 2017

Stryker Sustainability Solutions
Mr. Scott English
Staff Regulatory Affairs Specialist
1810 W. Drake Dr.
Tempe, Arizona 85283

Re: K161693
Trade/Device Name: Reprocessed HARMONIC ACE+7, 5 mm Diameter Shears with Advanced Hemostasis
Regulatory Class: Unclassified
Product Code: NLQ
Dated: January 24, 2017
Received: January 25, 2017

Dear Mr. English:

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" (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,

Jennifer R. Stevenson -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)*
K161693

Device Name
Reprocessed HARMONIC ACE® +7, 5mm Diameter Shears with Advanced Hemostasis

Indications for Use *(Describe)*
The Reprocessed HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis 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), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Advanced Hemostasis hand control button.

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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510(k) SUMMARY

Submitter:
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Contact:
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Date of Preparation: January 23, 2017

Name of Device:

Trade/Proprietary Name: Reprocessed HARMONIC ACE® +7, 5mm Diameter Shears with Advanced Hemostasis

Common Name: Scalpel, Ultrasonic, Reprocessed

Classification Information: Class: Unclassified
Unclassified Reason: Pre-Amendment
Product Code: NLQ

Predicate Devices:

Model Number	510(k) Number	510(k) Title	Original Manufacturer
HARH23 HARH36 HARH45	K132612	HARMONIC ACE+ Shears with Advanced Hemostasis	Ethicon Endo-Surgery

Device Description:

Reprocessed HARMONIC ACE®+7, 5mm Diameter Shears with Advanced Hemostasis are used for coagulation and mechanical transection of soft tissue during laparoscopic and open procedures. The devices consist of an ergonomic handle and 3 hand-controlled activation buttons. The handle includes a mechanism that provides both audible and tactile feedback indicating full closure. The instruments utilize Adaptive Tissue Technology which provides the generator with the ability to identify and monitor the instrument during use and enables the generator to modulate and adjust its power output as well as provide audible feedback to the user as appropriate. The only difference between the three (3) model numbers subject of this submission is the shaft length detailed in the table below.

Model Number	Description	Size
HARH23	Reprocessed HARMONIC ACE® +7 Shears with Advanced Hemostasis	5mm Diameter, 23cm Shaft Length
HARH36	Reprocessed HARMONIC ACE® +7 Shears with Advanced Hemostasis	5mm Diameter, 36cm Shaft Length
HARH45	Reprocessed HARMONIC ACE® +7 Shears with Advanced Hemostasis	5mm Diameter, 45cm Shaft Length

Each instrument is shipped with one sterile, single-use, disposable torque wrench.

Intended Use:

The Reprocessed HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis 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), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Advanced Hemostasis hand control button.

Summary of Technological Characteristics:

The design, materials, and intended use of Reprocessed HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis are equivalent to the predicate devices. The mechanism of action of the reprocessed device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. The differences between the reprocessed device and predicate device include a substitute tissue pad, new scalpel rod blade coating, and replacement Printed Circuit Board (PCB). There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis includes removal of adherent visible soil and decontamination. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations.

Performance Data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization Validation
- Functional Performance Tests
- Electrical Safety Testing
- Electromagnetic Compatibility Testing
- Software Validation
- Packaging Validation

The functional performance testing involved electrical safety and electromagnetic compatibility testing in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2, and verification/comparative testing (to the predicate device). The bench testing involved evaluation of the device's performance and ability to seal and divide vessels up to 7mm, including: thermal spread, transection time, burst pressure, device functionality, and device reliability.

Acute and chronic pre-clinical testing was conducted to evaluate thermal spread and the ability to achieve hemostasis of vessels and tissues.

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicates and operate as originally intended.

Conclusion:

Stryker Sustainability Solutions concludes that the Reprocessed HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis is at least as safe and effective as the predicate device as described herein.