March 16, 2021

Stryker Sustainability Solutions
Aphrodeja Crutch
Sr. Regulatory Affairs Specialist
1810 W. Drake Dr.
Tempe, Arizona 85283

Re: K202554
Trade/Device Name: Reprocessed HARMONIC ACE+ 7, 5 mm Diameter Shears with Advanced Hemostasis
Regulatory Class: Unclassified
Product Code: NLQ
Dated: February 16, 2021
Received: February 19, 2021

Dear Aphrodeja Crutch:

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:

OM	Model Number	Device Name/Description	Shaft Diameter	Shaft Length
Ethicon	HARH23	Harmonic ACE +7 Shears with Advanced Hemostasis	5mm	23cm
Ethicon	HARH36	Harmonic ACE +7 Shears with Advanced Hemostasis	5mm	36cm
Ethicon	HARH45	Harmonic ACE +7 Shears with Advanced Hemostasis	5mm	45cm

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)*
K202554

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.

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

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SECTION 5: 510(k) SUMMARY

Submitter:
Stryker Sustainability Solutions (SSS)
1810 W. Drake Drive
Tempe, Arizona 85283

Contact:
Aphrodeja Crutch, B.A., Pre-law/Legal Studies
Sr. Regulatory Affairs Specialist
404.993.1981 (c)
480-763-5310 (f)
aphrodeja.crutch@stryker.com

Date of Preparation: September 1, 2020

Name of Device:

Trade/Proprietary Name: Reprocessed Harmonic ACE® +7, 5mm Diameter Shears with Advanced Hemostasis (HARH23, HARH36, HARH45)

Common Name: Scalpel, Ultrasonic, Reprocessed

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

Model Numbers: HARH23, HARH36, HARH45

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, LLC

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.

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

Model Number	Description	Original Manufacturer
HARH23	HARMONIC ACE+7 Shears with Advanced Hemostasis 5mm Diameter, 23cm Length	Ethicon Endo-Surgery, LLC
HARH36	HARMONIC ACE+7 Shears with Advanced Hemostasis 5mm Diameter, 36cm Length	Ethicon Endo-Surgery, LLC
HARH45	HARMONIC ACE+7 Shears with Advanced Hemostasis 5mm Diameter, 45cm Length	Ethicon Endo-Surgery, LLC

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 in Comparison to the Predicate Devices:

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. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, SSS' 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.

Substantial Equivalence Table Ethicon Endo-Surgery HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis and Stryker Sustainability Solutions Reprocessed (SSS) HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis:

Characteristic	Ethicon Endo-Surgery HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis	Stryker Sustainability Solutions (SSS) Reprocessed HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis
Indications for Use	The 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.	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.
Contraindications for Use	• The instruments are not indicated for incising bone. • The instruments are not intended for contraceptive tubal occlusion.	• The instruments are not indicated for incising bone. • The instruments are not intended for contraceptive tubal occlusion.
Sterility	Sterile by Ethylene Oxide	Sterile by Ethylene Oxide
Pyrogen Free	No	No
Expiration Date	The expiration date is provided on the device package labels. The date of manufacture is not provided on the device package labels, thus, the shelf life is unknown.	The expiration date is provided on the device package labels. The expiration date is labeled as three (3) years from the date of manufacture.
Uses	Single Patient Use	Single Patient Use

Characteristic	Ethicon Endo-Surgery HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis	Stryker Sustainability Solutions (SSS) Reprocessed HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis
Generator	Generator G11 (GEN11) software version 2013_I or later	Generator G11 (GEN11) software version 2013_I or later
Device Materials	Refer to Table 10-2 for a list of patient-contacting materials.	Refer to Table 10-2 for a list of patient-contacting materials.
Device Packaging	Primary Packaging is comprised of a PETG sealed thermoformed tray. One (1) device is secured in the tray. An adhesive-coated DuPont 1073B Tyvek Lid is sealed to the tray to create a sterile barrier system. Secondary Packaging is comprised of solid bleached sulfate folding shelf carton. Six (6) Primary Packages are inserted into the Secondary Package. Tertiary Packaging is comprised of a corrugate shipping carton. One (1) Secondary Package is placed in a corrugate shipping carton.	Primary Packaging is comprised of a PETG sealed thermoformed tray. One (1) device is secured in the tray. An adhesive-coated DuPont 1073B Tyvek Lid is sealed to the tray to create a sterile barrier system. Secondary Packaging is comprised of solid bleached sulfate folding shelf carton. Six (6) Primary Packages are inserted into the Secondary Package. Tertiary Packaging is comprised of a corrugate shipping and sterilization carton. One (1) Secondary Package is placed in a corrugate shipping carton.
Substitute Components	Refer to Table 10-9 for list of substitute components.	Refer to Table 10-9 for list of substitute components.

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
    - Blade to Clamp Arm Angle
    - Actuating Trigger Force

  - MIN/MAX Button Activation Force
  - Advanced Hemostasis (AH) Button Activation Force
  - Rotation Knob Force – Actuating Trigger Disengaged
  - Rotation Knob Force – Actuating Trigger Engaged
  - Jaw Clamp Force
  - Tissue Retention Force
  - Shaft Straightness
  - ATT Functionality and Transection Time
  - Burst Pressure
  - Maximum Jaw and Shaft Temperature
  - Reliability Testing
- Electromagnetic Compatibility & Electrical Safety Testing
- Packaging Validation
- Pre-Clinical Testing
  - Acute Animal Study
  - Chronic Animal Study

The functional performance testing involved electrical safety and electromagnetic compatibility testing in accordance with IEC 60601-1-2 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.
The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate devices and operate as originally intended.

The Reprocessed HARMONIC ACE®+7, 5 mm Diameter Shears with Advanced Hemostasis are reprocessed no more than two (2) times. Each reprocessed device is tracked with a Stryker pad print on the device indicating the device has been reprocessed. On the second turn a line will be added on top of the original pad print indicating two reprocessing cycles. Once the device reaches the maximum number of reprocessing cycles, it is rejected and taken out of service. Reprocessing is conducted only by Stryker Sustainability Solutions. Stryker Sustainability Solutions restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:

Stryker Sustainability Solutions (SSS) 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.