February 20, 2024

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

Re: K233471
Trade/Device Name: Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 20cm length (HAR1120); Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 36cm length (HAR1136)
Regulation Number: 21 CFR Unclassified
Regulation Name:
Regulatory Class: Class II
Product Code: NLQ
Dated: October 23, 2023
Received: October 25, 2023

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 (the 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 available 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.
Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.02.20 14:09:02 -05'00'

Mark Trumbore, 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:

Models For This Submission

Description: Reprocessed HARMONIC 1100 Shears Model
Numbers: **HAR1120** and **HAR1136**

Physical Description/Specifications

The Reprocessed HARMONIC 1100 Shears sterile instruments are used for dissection, grasping, coagulation, and cutting between the blade and clamp arm. Each device model consists of an ergonomic handle, an integrated hand piece, and two energy delivery buttons:

- Energy Button – User can adjust power levels from 1-5
- Energy button with Advanced Hemostasis – For larger vessel sealing; user cannot adjust.

The instruments are available in two shaft lengths, 20 cm and 36 cm. An integrated audible and tactile mechanism in the handle indicates full trigger closure. The instrument has a clamp arm and coated curved blade that are deigned to work through a 5 mm trocar, through a 5mm reducer cap in a larger diameter trocar, or through an incision without the use of a trocar. The instrument shafts can be rotated continuously to facilitate visualization and access to targeted tissue. The two dashes on the instrument are intended to represent relative vessel size. The energy button is indicated for vessels up to 5 mm in diameter. When the energy button is used, cutting speed is the fastest. The energy button with Advanced Hemostasis is designed for larger vessels and is indicated for vessels up to 7 mm in diameter. When the Energy button with Advanced Hemostasis in used, cutting speed in reduced and hemostasis is maximized. The instrument utilizes Adaptive Tissue Technology. This provides the generator with the ability to identify and monitor the instrument during use, which enables the generator to modulate and adjust its power output as well as provide audible feedback to the user as appropriate.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233471

Device Name
Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 20cm Length (HAR1120);
Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 36cm Length (HAR1136)

Indications for Use *(Describe)*
The Reprocessed HARMONIC 1100 Shears 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, pediatric, gynecologic, urologic, thoracic, sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of veins up to and including 5 mm in diameter and arteries up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

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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510(k) Summary

Applicant Name:	Stryker Sustainability Solutions
Contact Person:	Aphrodeja Crutch Staff Specialist 1810 Drake Drive Tempe, AZ 85283 Phone: 404-993-1981 Email: Aphrodeja.Crutch@stryker.com
Device Trade Name:	Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 20cm Length (HAR1120); Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 36cm Length (HAR1136)
Common Name:	Instrument, Ultrasonic Surgical
Classification Name:	Instrument, Ultrasonic Surgical
Regulation Number:	Unclassified
Product Code:	NLQ
Device Class:	Class II
Date Prepared:	02/20/2024
Predicate Device:	HARMONIC 1100 Shears 20cm Length; HARMONIC 1100 Shears 36cm Length (K200841)
Predicate Product Code:	LFL
Description	The Reprocessed HARMONIC 1100 Shears instrument is a sterile, single patient use instrument used for dissection, grasping, coagulation, and cutting between the blade and clamp arm. It consists of an ergonomic handle with an integrated hand piece and two energy delivery buttons. 1) Energy button for power levels 1-5, and 2) Energy with Advanced Hemostasis button for large vessel sealing. The instrument is available in two shaft lengths (20 cm and 36 cm). An integrated audible and tactile mechanism in the grip housing indicates full trigger closure. The instrument has a clamp arm and coated curved blade that are designed to work

	through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without the use of a trocar. The instrument shafts can be rotated continuously to facilitate visualization and access to targeted tissue. The two dashes on the instrument are intended to represent relative vessel size. The Energy button is indicated for vessels up to 5mm in diameter. When the Energy button is used, cutting speed is the fastest. The energy button with Advanced Hemostasis is designed for larger vessels and is indicated for veins up to and including 5 mm in diameter and arteries up to and including 7 mm in diameter. When the Energy button with Advanced Hemostasis is used, cutting speed is reduced and hemostasis is maximized. The instrument utilizes Adaptive Tissue Technology. This provides the generator with the ability to identify and monitor the instrument during use, which enables the generator to modulate and adjust its power output as well as provide audible feedback to the user as appropriate. The HARMONIC 1100 Shears instrument is designed for use exclusively with the Generator 11 (GEN11) software version 2018-1 or later.
Indications for Use:	The Reprocessed HARMONIC 1100 Shears 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, pediatric, gynecologic, urologic, thoracic, sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of veins up to and including 5 mm in diameter and arteries up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.
Summary of Intended Use and Technologies:	The design, materials, and intended use of the Reprocessed HARMONIC 1100 Shears are equivalent to the predicate device. The mechanism of action of the reprocessed device is identical to the predicate device in that the same standard mechanical design, materials, and size is utilized. There are no changes to the claims, intended use, clinical application, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of the device 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. The only differences between the Reprocessed HARMONIC 1100 Shears and the predicate HARMONIC 1100 Shears are that the device is reprocessed, and some device components are replaced with equivalent components during the reprocessing operation.
Non-Clinical Testing:	Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed HARMONIC 1100 Shears. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization
- Electrical Safety and Electromagnetic Compatibility
- Functional Performance Tests
  - Blade to Clamp Arm Angle
  - Actuating Trigger Force
  - Energy Button Activation Force
  - Advanced Hemostasis (AH) Button Activation Force
  - Rotation Knob Force
  - Jaw Clamp Force
  - Tissue Retention Force
  - Leak Test
  - Bend Test
  - ATT Functionality and Transection Time
  - Burst Pressure
  - Maximum Jaw and Shaft Temperature
  - Reliability Cycling
  - Burst Pressure (Post-Reliability)
  - Maximum Jaw and Shaft Temperature (Post-Reliability)
  - Performance Attribute Testing

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).

Additionally, preclinical laboratory evaluations in an animal model were performed, which included acute and chronic survival studies. The studies were done to evaluate thermal spread and the ability to achieve hemostasis of vessels of the reprocessed device.

Clinical Testing: Clinical testing was not required for this submission.

Conclusion: The subject device Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 20cm Length (HAR1120); Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 36 cm Length (HAR1136) is substantially equivalent to the previously cleared predicate device HARMONIC 1100 Shears 20cm Length; HARMONIC 1100 Shears 36cm Length (K200841).