August 14, 2025

Stryker Sustainability Solutions
Scott English
Principal Regulatory Affairs Specialist
1810 W Drake Drive
Tempe, Arizona 85283

Re: K250898
Trade/Device Name: Reprocessed HARMONIC 700 Shears (HAR723/Reprocessed HARMONIC 700, 5mm Diameter Shears with Advanced Hemostasis x 23cm); Reprocessed HARMONIC 700 Shears (HAR736/Reprocessed HARMONIC 700, 5mm Diameter Shears with Advanced Hemostasis x 36cm); Reprocessed HARMONIC 700 Shears (HAR745/Reprocessed HARMONIC 700, 5mm Diameter SHears with Advanced Hemostasis x 45cm)
Regulatory Class: Unclassified
Product Code: NLQ
Dated: March 25, 2025
Received: July 25, 2025

Dear Scott English:

**(NOTE: Reprocessed SUD device types require a separate attachment of the list of all models cleared in the submission. A corrected SE letter will be required if the attachment is omitted.)**

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JAMES H. JANG -S
Digitally signed by JAMES H. JANG -S
Date: 2025.08.14 21:16:51 -04'00'

James Jang, Ph.D.
Acting 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 | HAR723 | HARMONIC 700 Shears with Advanced Hemostasis | 5mm | 23cm |
| Ethicon | HAR736 | HARMONIC 700 Shears with Advanced Hemostasis | 5mm | 36cm |
| Ethicon | HAR745 | HARMONIC 700 Shears with Advanced Hemostasis | 5mm | 45cm |

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K250898 |

Please provide the device trade name(s).

Reprocessed HARMONIC 700 Shears (HAR723/Reprocessed HARMONIC 700, 5mm Diameter Shears with Advanced Hemostasis x 23cm);
Reprocessed HARMONIC 700 Shears (HAR736/Reprocessed HARMONIC 700, 5mm Diameter Shears with Advanced Hemostasis x 36cm);
Reprocessed HARMONIC 700 Shears (HAR745/Reprocessed HARMONIC 700, 5mm Diameter SHears with Advanced Hemostasis x 45cm)

Please provide your Indications for Use below.

The Reprocessed HARMONIC 700, 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, pediatric, gynecologic, urologic, thoracic procedures, and sealing and transection of lymphatic vessels. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Advanced Hemostasis hand control button.

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K250898

# 510(k) Summary

Prepared on: 2025-08-12

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Stryker Sustainability Solutions |
| Applicant Address | 1810 W Drake Drive Tempe AZ 85283 United States |
| Applicant Contact Telephone | 901-451-1456 |
| Applicant Contact | Mr. Scott English |
| Applicant Contact Email | scott.english@stryker.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Reprocessed HARMONIC 700 Shears |
| Common Name | Single-Use Reprocessed Ultrasonic Surgical Instruments |
| Classification Name | Unclassified |
| Regulation Number | Pre-Amendment |
| Product Code(s) | NLQ |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K221790 | HARMONIC 700 Shears | LFL |
| K202554 | Reprocessed HARMONIC ACE +7, 5mm Diameter Shears with Advanced Hemostasis | NLQ |

## Device Description Summary

21 CFR 807.92(a)(4)

The reprocessed HARMONIC 700 with Advanced Hemostasis are designed for soft tissue incisions requiring bleeding control and minimal thermal injury. These instruments serve as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in various procedures, including general, pediatric, gynecologic, urologic, and thoracic surgeries, as well as in the sealing and transection of lymphatic vessels. They enable the coagulation of vessels up to 7 mm in diameter using the Advanced Hemostasis hand control button.

The instruments are available in three (3) shaft lengths: 23cm, 36cm, and 45cm lengths (HAR723, HAR736, and HAR745 respectively). Each shaft length has a diameter of 5 mm. The following features are essential to the control and performance of the device:

- An actuating trigger that closes and releases the clamp arm, securing tissue against the scalpel rod.
- MIN/MAX control buttons that adjust energy levels between minimum and maximum modes on the generator, enabling vessel sealing up to 5 mm.
- An Advanced Hemostasis button that allows the clinician to activate an additional energy mode, enabling vessel sealing up to 7 mm.
- A rotation knob to rotate the shaft 360° unless energy is being delivered.
- A torque wrench, a sterile, single-use component, used to apply the correct amount of torque when attaching the Hand Piece to the device.

The instruments connect to a generator and hand piece, which are essential for the device's functionality but are outside the scope of this submission.

The hand piece is a reusable component that attaches to the device and plugs into the generator, allowing the device to interface with the generator. This component contains the transducer, which converts electrical power to ultrasonic mechanical energy.

The generator is a reusable component that generates the electrical signal. Colored light indicators on the front panel of the generator visually communicate device status information to the user.

## Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Reprocessed HARMONIC 700, 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, pediatric,
gynecologic, urologic, thoracic procedures, and sealing and transection of lymphatic vessels. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Advanced Hemostasis hand control button.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use for the proposed device are the same in comparison to the predicate and reference devices.

## Technological Comparison 21 CFR 807.92(a)(6)

The design, materials, and intended use of the Reprocessed HARMONIC 700, 5mm Diameter Shears with Advanced Hemostasis 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 700, 5mm Diameter Shears with Advanced Hemostasis and the predicate HARMONIC 700 Shears are that the device is reprocessed, and some device components are replaced with equivalent components during the reprocessing operation.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed HARMONIC 700, 5mm Diameter Shears with Advanced Hemostasis. This included the following tests:

- Validation of Reprocessing
- Electrical Safety and Electromagnetic Compatibility
- Functional Performance Tests
  - o Jaw Clamp Force
  - o Tissue Retention Force
  - o Burst Pressure
  - o Maximum Jaw and Shaft Temperature
  - o Device Reliability
  - o ATT Functionality and Transection Time

Biocompatibility: There were no new patient-contacting materials or changes to the reprocessing process for the subject device, and all patient-contacting materials for the subject device were previously identified, provided, reviewed, and cleared in the reference device under K202554. The biocompatibility of the patient-contacting materials was previously tested based on ISO 10993-1: Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

Sterilization/Shelf-Life: No new changes have been made to the sterilization process or parameters; Reprocessed HARMONIC 700 Shears are sterilized to a 10-6 sterility assurance level (SAL) through an EO sterilization process in accordance with ISO 11135. There have been no new materials, either patient contacting or non-patient contacting, added to the subject device that would impact the previously validated sterilization process or parameters reported from the reference device cleared in K202554.

The functional performance testing involved electrical safety and electromagnetic compatibility testing in accordance with IEC 60601-1 and 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 burst pressure, maximum jaw and shaft temperature, device reliability, and ATT functionality.

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.

The results of bench testing and preclinical laboratory evaluations demonstrate that the Reprocessed HARMONIC 700, 5mm Diameter Shears with Advanced Hemostasis are at least as safe and effective as the predicate and perform as well as the identified legally marketed predicate device as described herein.