July 3, 2024

Stryker Sustainability Solutions
Scott English
scott.english@stryker.com
1810 West Drake Drive
Tempe, Arizona 85283

Re: K241606
Trade/Device Name: Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 20cm Length (HAR1120);
Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 36cm Length (HAR1136)
Regulatory Class: Unclassified
Product Code: NLQ, LFL
Dated: June 4, 2024
Received: June 4, 2024

Dear Scott 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 (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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.07.03 16:05:30 -04'00'

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	Shaft Diameter	Shaft Length
Ethicon	H**AR1120**	HARMONIC 1100 Shears	5 mm	20 cm
Ethicon	HAR1136	HARMONIC 1100 Shears	5 mm	36 cm

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241606

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 vessels 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

Prepared on: 2024-06-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Stryker Sustainability Solutions
Applicant Address	1810 West Drake Drive Tempe AZ 85283 United States
Applicant Contact Telephone	9014511456
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 1100 Shears, 5mm Diameter, 20cm Length (HAR1120); Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 36cm Length (HAR1136)
Common Name	Reprocessed HARMONIC 1100 Shears
Classification Name	Single-Use Reprocessed Ultrasonic Surgical Instruments
Regulation Number	N/A
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
K233471	Reprocessed HARMONIC 1100 Shears, 5mm Diameter, 20cm le	NLQ
K200841	Harmonic 1100 Shears, 20cm length, Harmonic 1100 36cm lengt	LFL

Device Description Summary

21 CFR 807.92(a)(4)

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 vessels up to 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.

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

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 vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

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

The difference in indications for use does not constitute a new intended use. The predicate indications for use were limited to coagulation of vessels, up to 5 mm in diameter for veins and up to 7 mm in diameter for arteries, using the Energy button with Advanced Hemostasis. The subject device is indicated for for coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis. The inclusion of veins up to and including 7 mm in diameter is supported by additional chronic animal study data per the recommendation of FDA reviewers of K233471.

Technological Comparison 21 CFR 807.92(a)(6)

There are no differences in the technological characteristics (i.e., design, material, chemical composition, principal of operation, energy source, etc.) The subject device is the same device as the predicate. The only difference is the expansion of the indications for use.

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

Supplemental chronic 21-day survival studies were completed to assess the long-term seal quality of veins up to and including 7 mm in diameter. The data supports the expansion of the indications for use to include coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.