August 19, 2020

Surgical Instrument Service and Savings, Inc. (dba Medline ReNewal)
Gail Gassner
Quality Assurance Specialist II
1500 NE Hemlock Ave
Redmond, Oregon 97756

Re: K193563/S001
Trade/Device Name: Medline ReNewal Reprocessed Harmonic ACE+7 Shears
Regulatory Class: Unclassified
Product Code: NLQ
Dated: July 20, 2020
Received: July 21, 2020

Dear Gail Gassner:

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

K193563

Reprocessed Single-Use Device Models Included in Submission:

Device Model	Device Name	Original Manufacturer
HARH23	Harmonic ACE+7 Shears (5-mm diameter x 23-cm long shaft, 360° rotation)	Ethicon
HARH36	Harmonic ACE+7 Shears (5-mm diameter x 36-cm long shaft, 360° rotation)	Ethicon
HARH45	Harmonic ACE+7 Shears (5-mm diameter x 45-cm long shaft, 360° rotation)	Ethicon

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)*
K193563

Device Name
Medline ReNewal Reprocessed Harmonic ACE+7 Shears (HARH23, HARH36, HARH45)

Indications for Use *(Describe)*
The Medline ReNewal Harmonic ACE+7 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, 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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K193563

Reprocessed Single-Use Device Models Included in Submission:

Device Model	Device Name	Original Manufacturer
HARH23	Harmonic ACE+7 Shears (5-mm diameter x 23-cm long shaft, 360° rotation)	Ethicon
HARH36	Harmonic ACE+7 Shears (5-mm diameter x 36-cm long shaft, 360° rotation)	Ethicon
HARH45	Harmonic ACE+7 Shears (5-mm diameter x 45-cm long shaft, 360° rotation)	Ethicon

5.0 510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR § 807.92.

Submitter/ Owner	Surgical Instrument Service and Savings (dba Medline ReNewal) 1500 NE Hemlock Ave., Redmond, OR 97756	
Contact/ Prepared by	Gail Gassner Quality Assurance Specialist II, Quality Assurance/Regulatory Affairs P: 541-516-4193 • F: 541-923-3375 • E: ggassner@medline.com	
Date Prepared	December 20, 2019	
Device Name and Classification	Proprietary/Trade Name:	Medline ReNewal Reprocessed Harmonic ACE+7 Shears models HARH23, HARH36, and HARH45
	Common or Usual Name	Reprocessed ultrasonic scalpel
	Regulatory Name/Reference	Electrosurgical cutting and coagulation device and accessories reprocessed, 21 CFR § 878.4400
	Regulatory Class	Unclassified
	Product Code	NLQ
	Panel	General & Plastic Surgery
Predicate Device	510(k) Number	K132612
	Proprietary or Trade Name	HARMONIC ACE+ SHEARS 23 CM LENGTH WITH ADVANCED HEMOSTASIS, HARMONIC ACE + LAPAROSCOPIC SHEARS 36 CM LENGTH WITH ADVANCE
	Common or Usual Name	Ultrasonic surgical instrument
	Regulatory Name/Reference	Electrosurgical cutting and coagulation device and accessories reprocessed, 21 CFR § 878.4400
	Regulatory Class	Unclassified
	Product Code	LFL
	Panel	General & Plastic Surgery
	Manufacturer	Ethicon Endo-Surgery, LLC 4545 Creek Road, Cincinnati, OH 45242
Device Description	The Medline ReNewal Reprocessed Harmonic ACE+7 Shears (models HARH23, HARH36, and HARH45) are used for coagulation and mechanical transection of soft tissue during laparoscopic and open procedures. The devices allow the surgeon to grasp, coagulate, and transect soft tissue with a single instrument. The devices are hand-actuated with a shaft and tissue effector that can be rotated. The energy delivery can be activated with hand activation or with an optional generator foot switch.	
Indications for use	The Medline ReNewal Harmonic ACE+7 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, 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.
Technological Characteristics	The technological characteristics and the fundamental scientific technology of the subject devices are equivalent to the predicate device. The proposed devices are a reprocessed version of the predicate devices. K132612 Ethicon Harmonic ACE+7 Shears was used as the primary predicate to support intended use, technological characteristics, and functional performance specifications.
Performance Testing	The functional characteristics of the proposed devices have been evaluated and found to be equivalent to the predicate devices based on the following tests: • electrical safety and electromagnetic compatibility in accordance with IEC 60601-1 and 60601-1-2; • simulated use; • device integrity; • handle operation; • shaft knob rotation; • device recognition; • cutting time; • thermal analysis characterization; • tissue sticking; • burst pressure; • histopathology; • seal quality; • Cleaning: o protein, o carbohydrates, o endotoxin; • Biocompatibility: o cytotoxicity, o sensitization, o irritation, o materials-mediated pyrogen, and o acute systemic toxicity; • performance qualification; and • sterilization validation.

Summary Table: Predicate and Medline ReNewal Reprocessed Harmonic ACE+7 Shears device comparison chart.

Device Characteristics	**Predicate**	**Proposed**	**Comparison**
	Ethicon Harmonic ACE+7 Shears with Advanced Hemostasis	**Medline ReNewal Reprocessed Harmonic ACE+7 Shears**	**As Stated**
510(k)	K132612	K193563	N/A
Model Numbers	HARH23, HARH36, HARH45	HARH23, HARH36, HARH45	Same
Common Name	Instrument, Ultrasonic Surgical	Scalpel, Ultrasonic, Reprocessed	As stated

Regulation No.	21 CFR § 878.4400	21 CFR § 878.4400	Same
Regulatory Class	Unclassified	Unclassified	Same
Product Code	LFL	NLQ	As stated
Indications for Use	The Ethicon Harmonic ACE+ 7 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 Medline ReNewal Reprocessed Harmonic ACE+ 7 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.	Same

Summary Table: Predicate and Medline ReNewal Reprocessed Harmonic ACE+7 Shears device comparison chart (concluded).

Device Characteristics	Predicate	Proposed	Comparison
	Ethicon Harmonic ACE+7 Shears with Advanced Hemostasis	**Medline ReNewal Reprocessed Harmonic ACE+7 Shears**	**As stated**
Power Platform[a]	• HARH23 = Ethicon Endo-Surgery Generator G11, model GEN11 • HARH36 = Ethicon Endo-Surgery Generator G11, model GEN11 • HARH45 = Ethicon Endo-Surgery Generator G11, model GEN11	• HARH23 = Ethicon Endo-Surgery Generator G11, model GEN11 • HARH36 = Ethicon Endo-Surgery Generator G11, model GEN11 • HARH45 = Ethicon Endo-Surgery Generator G11, model GEN11	Same
Technological Characteristics	The Harmonic ACE+7 Shears works in conjunction with the Ethicon GEN11 generator. The device connects to the GEN11 with a handpiece and can be operated using finger switches on the handle or with a foot pedal. Communication with the GEN11 is facilitated and data is stored by flex circuitry in the device handle.[b] A mechanical trigger actuates the jaws.	The Harmonic ACE+7 Shears works in conjunction with the Ethicon GEN11 generator. The device connects to the GEN11 with a handpiece and can be operated using finger switches on the handle or with a foot pedal. Communication with the GEN11 is facilitated and data is stored by ReNewal Key-integrated flex circuitry in the device handle. A mechanical trigger actuates the jaws.	As stated
[a] The Ethicon Endo-Surgery Generator G11, model GEN11 generator was cleared under K101990. The generator will not be reprocessed by Medline ReNewal. It is not a part of this submission. [b] The flex circuitry in the OEM Harmonic ACE+7 Shears limits the device to a single use. The ReNewal Key-integrated flex circuitry in the reprocessed Harmonic ACE+7 Shears enables an additional use.			
Conclusion	Based on comparisons of the indications for use, intended use, technological characteristics, and performance data to the predicate devices, Medline ReNewal Reprocessed Harmonic ACE+7 Shears models HARH23, HARH36, and HARH45 are substantially equivalent to the predicate devices.		