February 28, 2023

Ethicon Endo-Surgery, LLC
Hillary Lewis
Regulatory Affairs Specialist
4545 Creek Road
Cincinnati, Ohio 45242

Re: K221790
Trade/Device Name: HARMONIC 700 Shears
Regulatory Class: Unclassified
Product Code: LFL
Dated: January 26, 2023
Received: January 27, 2023

Dear Hillary Lewis:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.02.28 15:44:07 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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Center for Devices and Radiological Health

Enclosure

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)*
K221790

Device Name
HARMONIC™ 700 Shears

Indications for Use *(Describe)*

The 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.

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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510(k) Summary

Company Ethicon Endo-Surgery, LLC
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Date Prepared

28 February 2023

Device and Classification Information – HARMONIC 700 Shears

Trade Name:	HARMONIC® 700 Shears
Common Name:	Instrument, Ultrasonic Surgical
Classification Regulation:	Unclassified
Classification Name:	Instrument, Ultrasonic Surgical
Product Code:	LFL
Device Class:	Class II
Panel:	79, General and Plastic Surgery

Device Description – HARMONIC 700 Shears

The HARMONIC 700, 5 mm Diameter Shears with Advanced Hemostasis are intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments are sterile, single-patient-use instruments consisting of an ergonomic grip housing assembly with hand control buttons (MIN for minimum power level, MAX for maximum power level, and Advanced Hemostasis for large vessel sealing).

An integrated audible and tactile mechanism in the grip housing indicates full trigger closure. The instruments have 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 360º to facilitate visualization and access to targeted tissue. The three dashes on the instrument are intended to represent

relative vessel size. The MAX button is typically used for smaller vessels where cutting speed is the fastest. The MIN button is typically used in slightly larger vessels and has reduced cutting speed. It is indicated for vessels up to 5 mm in size. The Advanced Hemostasis button is designed for larger vessels and is indicated for vessels up to 7 mm in size. In this mode, cutting speed is further reduced and hemostasis is maximized. This design is common to both subject and predicate devices and has been evaluated by FDA in K132612 (predicate device), K160752 (HARMONIC HD1000i), and K200841 (HARMONIC 1100).

The instruments utilize 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 700, 5 mm Diameter Shears with Advanced Hemostasis are designed for use exclusively with the Generator G11 (GEN11) software version 2018-1 or later, last cleared under K200841 on 11 May 2020.

Indications for Use – HARMONIC 700 Shears

The 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.

Intended Use – HARMONIC 700 Shears

The subject device and the predicate device have the same intended use. Both devices are ultrasonic surgical instruments intended to cut and control bleeding from soft tissues and vessels during open and endoscopic procedures. Both are intended for use as an adjunct to or substitute for electrosurgery, lasers or manual scalpels in several different clinical specialties, for sealing and transecting vessels, and for dissection. Both devices coagulate vessels up to and including 7 mm in diameter. Both devices are a surgical tool used by surgeons during open and endoscopic procedures that share the same function to simultaneously cut and cauterize tissue and vessels using ultrasonic vibration. Both devices have the same tissue/body contact and limited duration of use from a biocompatibility perspective.

Predicate Device and Substantial Equivalence Comparison – HARMONIC 700 Shears

For purposes of the substantial equivalence comparisons, the following predicate device was selected:

- HARMONIC ACE+7 Shears with Advanced Hemostasis cleared under K132612 on 17 October 2013

The purpose of this 510(k) submission is to notify the Agency of the intent to commercialize a new device, HARMONIC 700 Shears.

Technological Characteristics: The fundamental technological characteristics (i.e., design, material, chemical composition, energy source) of the HARMONIC 700 Shears are equivalent to the predicate. The subject device uses a different version of GEN11 software (2018-1) than the predicate (2013_1).

Comparison of Technological Characteristics with the Predicate Device:

Performance Data: Verification testing for the design modifications was provided and raises no new issues of safety or effectiveness.

Biocompatibility Testing: There were no new patient-contacting materials for the subject device, and all patient contacting materials for the subject device were previously identified, provided, reviewed, and cleared in the predicate device under K132612. The biocompatibility of the patient contact materials was previously tested based on ISO 10993-1: Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

Electromagnetic Compatibility and Electrical Safety: Electrical safety testing and electromagnetic compatibility was conducted for the subject device in accordance with IEC 60601-1-2 for electromagnetic compatibility and IEC 60601-1 and IEC 60601-2-2 for electrical safety.

Sterilization/Shelf-Life: No new changes have been made to the sterilization process or parameters; 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 predicate device, K132612. The designated shelf-life for HARMONIC 700 Shears is 5-years.

Bench Testing: Tissue Pad Life, Tissue Pad Removal Force, Instrument Grasping Force, and Sealed Vessel Burst Pressure were evaluated on HARMONIC 700 Shears to determine substantial equivalence to the predicate device. The mechanical design between the subject and predicate device is identical. Supplemental Sealed Vessel Burst Pressure testing evaluated the device performance and ability to divide and seal vessels. Porcine carotid arteries were utilized in this testing. Thermal Spread bench top testing evaluated vessels utilizing the MIN mode, MAX mode, and Advanced Hemostasis. The subject device performed as expected, the results of the bench testing demonstrated substantial equivalence with the predicate device in vessels up to and including 7 mm.

Preclinical Studies:

Acute Animal Testing

Acute Animal Testing was performed in three acute porcine studies to evaluate the three lengths of the subject device, HARMONIC 700 Shears as compared to the predicate (control) device, HARMONIC ACE+7 Shears. Arteries, veins, and pedicles of various sizes were evaluated to determine equivalency of the subject device to the predicate. Additionally, the thermal spread to the vessel/vessel pedicles was assessed. Vessels were transected and sealed using the MIN/MAX Modes and the Advanced Hemostasis Mode. The results of the acute studies demonstrated no statistical differences in the intra-operative tissues effects between the three devices lengths. Results of the testing between the three lengths supported the equivalency of the HARMONIC 700 Shears to the predicate device.

Chronic Animal Testing

Chronic Animal Testing was performed in a survival study with the subject device, HARMONIC 700 Shears as compared to the predicate device. Blood vessels and blood vessel pedicles were transected and sealed. The results of the survival study demonstrated the subject device performed equivalent to the predicate.

Clinical Testing

This premarket notification does not rely on human clinical trial data to demonstrate substantial equivalence

Conclusion: In demonstrating substantial equivalence of the subject HARMONIC 700 Shears to the predicate device, Ethicon Endo-Surgery, LLC. evaluated the indication for use, intended use and technological characteristics. The HARMONIC 700 Shears, as indicated for vessel/vessel pedicles up to and including 7 mm, are substantially equivalent to the predicate device; they share the same intended use and equivalent technological characteristics. The subject device is as safe and effective as the predicate device.