February 28, 2020

Ethicon Endo-Surgery, LLC
% Brian Godwin
Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road, ML39
Cincinnati, Ohio 45242

Re: K191555
Trade/Device Name: HARMONIC HD 1000i Shears
Regulation Number: Unclassified
Regulatory Class: Class II
Product Code: LFL
Dated: June 7, 2019
Received: February 13, 2020

Dear Brian Godwin:

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

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)*
K191555

Device Name
Harmonic HD 1000i Shears

Indications for Use *(Describe)*
The Harmonic HD 1000i Shears instrument is 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 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.

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510(k) SUMMARY

Applicant Information

Applicant: Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact: Brian Godwin, RAC
Manager, Regulatory Affairs
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Telephone: (513) 337-3623
Email: BGodwin@ITS.JNJ.com

Date of Preparation: February 28, 2020

510(k) Number: K191555

Device and Classification Information

Trade Name:	HARMONIC® HD 1000i Shears
Common Name:	Instrument, Ultrasonic Surgical
Classification Regulation:	Unclassified
Product Code:	LFL – Instrument, Ultrasonic Surgical
Class:	Class II
Panel:	General and Plastic Surgery

Device Description

The HARMONIC HD 1000i Shears are sterile, single-patient use devices for the dissection, grasping, coagulation, and cutting of soft tissue between the blade and clamp arm. The device consists of an ergonomic grip housing assembly with two-hand control buttons: 1) Energy button

for power levels 1-5, and 2) Energy with Advanced Hemostasis button for large vessel sealing. The device is available in two shaft lengths (20 cm and 36 cm), and both device shafts can be rotated continuously to facilitate visualization and access to targeted tissue.

An integrated audible and tactile mechanism in the grip housing indicates full trigger closures. The device has a clamp arm and coated curved blade that is 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 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 with Advanced Hemostasis button is designed for larger vessels and is indicated for vessels up to 7 mm in diameter. When the Energy with Advanced Hemostasis button is used, cutting speed is reduced and hemostasis is maximized. The device utilizes Adaptive Tissue Technology (the technological characteristics of which were first cleared under K120729 on May 17, 2012 and incorporated into multiple Ethicon devices). 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 HD 1000i Shears are designed for use exclusively with the Ethicon Generator 11 (GEN 11), last cleared under K160554 on September 9, 2016.

Indication for Use

The following is the indication for use for the HARMONIC HD 1000i Shears including in this 510(k) submission:

> *The Harmonic HD 1000i Shears instrument is 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 Energy button with Advanced Hemostasis.*

Intended Use

The new 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 a number of different clinical specialties, for sealing and transecting vessels, and for dissection. Both device 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 Identification and Substantial Equivalence Comparison

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

- HARMONIC HD 1000i Shears cleared under K160752 on June 29, 2016

The purpose of this 510(k) submission is notify the Agency of design changes since the baseline 510(k), K160752 cleared on June 29, 2016.

Technological Characteristics: Minor design modifications have been made to improve device performance. The fundamental technological characteristics (ie, design, material, chemical composition, energy source) of the HARMONIC HD 1000i Shears are equivalent to the predicate.

Performance Data: Minor design modifications have been made to improve device performance. Verification testing for the design modifications was provided to demonstrate safety and effectiveness.

Conclusion: In establishing substantial equivalence of the HARMONIC HD 1000i Shears to the predicate device, Ethicon Endo-Surgery evaluated the indication for use, intended use and technological characteristics. The HARMONIC HD 1000i Shears are substantially equivalent to the predicate device because they share the same intended use and equivalent technological characteristics. The subject device is as safe and effective as the predicate device.

Characteristic/Specification	***HARMONIC HD 1000i Shears Subject Device K191555***	***HARMONIC HD 1000i Shears Predicate Device K160752***
Product Code	Same	
Sterility Method	Same	
Sterility Assurance Level	Same	
Patient Use	Same	
Maximum Power	Same	
Maximum Voltage	Same	
Maximum Current	Same	
Blade Frequency	Same	
Blade Amplitude – HARHD20	Same	

Characteristic/Specification	***HARMONIC HD 1000i Shears Subject Device K191555***	***HARMONIC HD 1000i Shears Predicate Device K160752***
Blade Amplitude – HARHD36	Same	
Shaft Diameter	Same	
Active Blade Length	Same	
Blade Design/Geometry	Same	
Shaft Lengths	Same	
Packaging	Same	
Energy Activation Method	Same	
Maximum Indicated Vessel Size	Same	
Handle Type	Same	
Identification	Same	
Compatible Generator	Same	
Modality	Same	
Available Generator Tones	Same	
Energy Buttons	Same	
Energy Buttons for Advanced Hemostasis	Same	