May 11, 2020

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

Re: K200841
Trade/Device Name: Harmonic 1100 Shears, 20cm length, Harmonic 1100 36cm length, Generator G11
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, LFL
Dated: March 30, 2020
Received: March 31, 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)*

K200841

Device Name
HARMONIC 1100 Shears
Ethicon Generator G11

Indications for Use *(Describe)*

HARMONIC 1100 Shears

The HARMONIC 1100 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, 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.

Ethicon Generator G11

The Generator G11 provides radiofrequency power to drive ENSEAL electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive HARMONIC ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired.

ENSEAL and HARMONIC instruments, when used with the Generator G11, have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

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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Contact Brian Godwin, RAC
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Date Prepared

30 March 2020

Device and Classification Information – HARMONIC 1100 Shears

Trade Name:	HARMONIC® 1100 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 1100 Shears

The HARMONIC 1100 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 1100 Shears are designed for use exclusively with the Ethicon Generator 11 (GEN11), last cleared under K160554 on September 9, 2016.

Indications for Use – HARMONIC 1100 Shears

The HARMONIC 1100 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, 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.

Intended Use – HARMONIC 1100 Shears

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 and Substantial Equivalence Comparison – HARMONIC 1100 Shears

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

- HARMONIC HD 1000i Shears cleared under K191555 on 28 February 2020

The purpose of this 510(k) submission is notify the Agency of the intent to commercialize a new device, HARMONIC 1100 Shears.

Technological Characteristics: The fundamental technological characteristics (ie, design, material, chemical composition, energy source) of the HARMONIC 1100 Shears are equivalent to the predicate. The subject device uses a different version of software (2018-1) than the predicate (2016-1).

Performance Data: Verification testing for the design modifications was provided to demonstrate safety and effectiveness.

Conclusion: In establishing substantial equivalence of the subject HARMONIC 1100 Shears to the predicate device, Ethicon Endo-Surgery evaluated the indication for use, intended use and technological characteristics. The HARMONIC 1100 Shears 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.

Device and Classification Information – Generator G11	
Trade Name:	Generator G11
Common Name:	Electrosurgical and Ultrasonic Surgical Generator
Classification Regulation:	21 CFR 878.4400, 21 CFR 884.4120, and Unclassified (LFL)
Classification Name:	Electrosurgical & Ultrasonic Surgical Generator; Electrosurgical, Gynecologic (and Accessories); Instrument, Ultrasonic Surgical
Product Code:	GEI, HGI, LFL
Device Class:	Class II
Panel:	79, General and Plastic Surgery

Device Description – Generator G11

The Generator G11 supplies energy to the HARMONIC® and ENSEAL® surgical instruments. The generator uses a touchscreen display interface and has a unique receptacle port that accepts either a HARMONIC or an ENSEAL instrument. Connectors (HGA11 for HARMONIC and EGA11 for ENSEAL) are used to enable the generator to power legacy instruments.

All ENSEAL and HARMONIC devices compatible with the generator and provided by Ethicon and authorized manufacturers undergo an extensive verification and validation process. The Ethicon Endo-Surgery Generator G11 System is not designed to operate unauthorized devices.

Such use is not in accordance with the design and use parameters, instructions and guidelines for the product.

Indications for Use – Generator G11

The Generator G11 provides radiofrequency power to drive ENSEAL electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive HARMONIC ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired.

ENSEAL and HARMONIC instruments, when used with the Generator G11, have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

Intended Use – Generator G11

The Generator G11 is intended to provide power to ENSEAL electrosurgical instruments and HARMONIC ultrasonic surgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues.

Predicate Device and Substantial Equivalence Comparison – Generator G11

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

- Generator G11, last cleared under K160554 on 09 September 2016

The purpose of this 510(k) submission is notify the Agency of the intent to commercialize a new software version for Generator G11 device.

Technological Characteristics: The fundamental technological characteristics (ie, design, material, chemical composition, energy source) of the Generator G11 are equivalent to the predicate. The subject device uses a different version of software (2018-1) than the predicate (2016-1).

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 subject Generator G11 to the predicate device, Ethicon Endo-Surgery evaluated the indication for use, intended use and technological characteristics. The Generator G11 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.