DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 29, 2016

Ethicon Endo-Surgery, LLC
% Mr. David Locke
Senior Regulatory Affairs Program Lead
Ethicon Endo-surgery, LLC
475 Calle C
Guaynabo, PR 00969

Re: K160752
Trade/Device Name: Harmonic HD 1000i Shears 20 cm Length, Harmonic HD 1000i Shears 36 cm Length
Regulatory Class: Unclassified
Product Code: LFL
Dated: May 20, 2016
Received: May 23, 2016

Dear Mr. Locke:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson
-A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160752

Device Name
HARMONIC HD 1000i Shears 20 cm Length, HARMONIC HD 1000i Shears 36 cm Length

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

Company Ethicon Endo-Surgery, LLC
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Contact David Locke, DRSc, MS, RAC
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Date Prepared

June 27, 2016

Device Name

Trade Name: HARMONIC HD 1000i Shears 20 cm Length, HARMONIC HD 1000i Shears 36 cm Length

Common Name: Instrument, Ultrasonic Surgical

Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code: LFL)

Regulatory Class

Unclassified

Predicate Device

HARMONIC ACE®+ Shears with Advanced Hemostasis, cleared under K132612 on October 17th, 2013

Device Description

The HARMONIC HD 1000i Shears are a sterile, single patient use device used for dissection, grasping, coagulation, and cutting between the blade and clamp arm. It 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 closure. 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 blade used in the HARMONIC HD 1000i Shears has a slightly different blade design than that of the predicate device, the HARMONIC ACE+ Shears with Advanced Hemostasis (cleared under K132612 on October 17, 2013), and is also slightly longer and more tapered than the predicate device. Additionally, two dashes have been added to the device which are intended to represent relative vessel size.

The distal/front Energy button is indicated for vessels up to 5 mm in diameter. The Energy with Advanced Hemostasis button (the Green button), which is found on the side of the device handle, is designed for larger vessels and is indicated for vessels up to 7 mm in diameter. The device utilizes Adaptive Tissue Technology (the technological characteristics of which were first cleared under K120729 on May 17, 2012). This technology provides the generator with the ability to identify and monitor the instrument during use.

The HARMONIC HD 1000i Shears are designed for use exclusively with the Ethicon Generator 11 (GEN11).

Indications for Use

Indications
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.

Contraindications

- *The instruments are not indicated for incising bone.*
- *The instruments are not intended for contraceptive tubal occlusion.*

Technological Characteristics

The Ethicon Endo-Surgery HARMONIC HD 1000i Shears incorporate the same technological characteristics as that of the ultrasonic predicate device, HARMONIC ACE+ Shears with Advanced Hemostasis. Both the subject and predicate devices use an EEPROM memory chip that stores device identification, usage tracking, and operating parameters for use by the Generator G11 that provides power for the HARMONIC HD 1000i Shears. Further, both devices have an ergonomic grip housing assembly which allows for manual closure of the jaw and the devices contain buttons which allow for the manual application of energy. To as where the predicate HARMONIC ACE+ Shears with Advanced Hemostasis contains three buttons allowing for manual energy activation, the subject HARMONIC HD 1000i Shear only contains two buttons, allowing for manual energy activation.

Performance Data

Bench testing and laboratory evaluations in an animal model including acute and 30-day chronic survival studies were conducted to demonstrate that the HARMONIC HD 1000i performs as intended.

Sterilization

Both the subject and predicate devices are sterilized via ethylene oxide and both devices are sterilized to the same sterility assurance level.

Biocompatibility Testing

Biocompatibility testing was not required for this submission as no new materials were introduced on this device.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the HARMONIC HD 1000i device. The system was shown to comply with IEC 60601-1-2:2007 for electromagnetic compatibility and IEC 60601-1:2005 for electrical safety.

Bench Testing

Tissue pad life, tissue pad removal force, instrument grasping force and sealed vessel burst test were evaluated for HARMONIC HD 1000i device to support substantial equivalence to the predicate device. Data generated from the bench testing met the predetermined acceptance criteria.

Acute Animal Testing

Testing was performed in an acute porcine study with the HARMONIC HD 1000i device vs. the predicate device to demonstrate that the tissue effects were not different than the predicate device. Evaluations included hemostatic transection of vessels and vessel pedicals ≤ 5 mm using the Energy button and ≤ 7 mm in diameter using the Energy button with Advanced Hemostasis. Additional head-to-head testing included lateral thermal damage, tissue dissection, and back cutting on the porcine model. The results of the acute studies demonstrated that the tissue effects were not different than the predicate device.

Survival Animal Testing

Testing was performed in a chronic survival study with the HARMONIC HD 1000i device vs. the predicate device to demonstrate that the tissue effects were not different than the predicate device. Evaluations included hemostatic transection of vessels and vessel pedicals ≤ 5 mm using the Energy button and ≤ 7 mm in diameter using the Energy button with Advanced Hemostasis in splenectomy and carotid artery procedures. The chronic survival studies included a blood pressure challenge immediately prior to necropsy as an overstress test of the healed vessel seals.

The results of the survival studies demonstrated that the tissue effects were not different than the predicate device.

Clinical Studies

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

Conclusion

The results of the bench testing and laboratory evaluations in an animal model demonstrate that the HARMONIC HD 1000i device is as safe and effective and performs as well as the identified legally marketed predicate devices for cutting, coagulating and dissecting soft tissue and sealing vessels up to 7 mm in diameter.