DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 4, 2016

Ethicon Endo-Surgery, LLC
Mr. Brian Godwin
Senior Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242

Re: K151136
Trade/Device Name: HARMONIC Hook
Regulatory Class: Unclassified
Product Code: LFL
Dated: February 2, 2016
Received: February 3, 2016

Dear Mr. 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. 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)*

K151136

Device Name

HARMONIC® Hook

Indications for Use *(Describe)*

The HARMONIC Hook instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

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 K151136

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Date Prepared 28 April 2015

Device Name

Trade Name: HARMONIC® Hook
Common Name: Instrument, Ultrasonic Surgical
Catalog Code: HARBH32

Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code LFL)

Regulatory Class
Unclassified

Predicate Device

HARMONIC 5mm instrument, cleared under K990362 on 17 September 1999
HARMONIC 5mm Instrument, last cleared under K060245 on 7 April 2006

The predicate device characteristics are described in K990362 when it was first cleared. The predicate device had an indication expansion in K060245.

Device Description

The HARMONIC Hook instrument is a sterile, single patient use instrument, consisting of a 5 mm titanium blade. The instrument allows for the cutting of soft tissue and coagulation of vessels up to and including 2 mm in diameter. The working length of the HARMONIC Hook instrument is 32 cm.

The HARMONIC Hook instrument works with the Generator G11 as part of a system. The device system has four essential parts: the Generator G11 (GEN11), the footswitch (FSW11), the handpiece (HPBLUE), and the HARMONIC Hook (HARBH32). The HARMONIC Hook has an

internal torque wrench for assembly to the HPBLUE handpiece. The HPBLUE handpiece connects the HARMONIC Hook device to the Generator G11, and converts electrical energy into mechanical motion (ultrasonic energy). The high-frequency mechanical vibration at 55.5 kHz of the HARMONIC Hook blade transects, dissects, and coagulates tissue, sealing vessels up to 2 mm. This ultrasonic vibration, a form of mechanical energy, does not allow electricity to pass to or through the patient.

The HARMONIC Hook can be operated using the 360º circumferential activation switch on the handle housing or the right footswitch pedal (MAX) of the footswitch (FSW11). Only the right footswitch pedal is active when using the device; the left footswitch pedal (MIN) is not active when using HARMONIC Hook.

Indications for Use

The HARMONIC Hook instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, gynecologic, exposure to orthopedic structures (such as spine and joint space), and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

Technological Characteristics

The subject and predicate devices use the same ultrasonic technology to perform their intended use. The handpiece converts electrical energy into ultrasonic vibration. The HARMONIC Hook uses the HPBLUE handpiece while the predicate device uses the HP054 handpiece and the handswitch adaptor HSA08. Both the HPBLUE handpiece and the HP054 handpiece serve the same functional purpose to convert electrical energy from the Generator G11 to mechanical energy (ultrasonic energy) at the end effector for each device.

A few technological differences were identified between the subject and predicate devices, attributable to the respective design of each. Of the differences, three were noted in the submission, summarized below. These differences were found to not affect safety or effectiveness through demonstration of effective performance and equivalency to relevant aspects of the predicate device, conformance to industry safety and performance standards, and bench and preclinical evaluations.

Blade Frequency/Displacement

The blade frequency and displacement between the subject and predicate devices are slightly different, but is not clinically relevant with regards to tissue effect.

Sterilization

The subject devices are sterilized via ethylene oxide and the predicate devices are sterilized via gamma radiation; both devices are sterilized to the same sterility assurance level.

Performance Data

Bench testing and laboratory evaluations were conducted to demonstrate that the HARMONIC Hook performed as intended.

Biocompatibility Testing

The biocompatibility evaluation for HARMONIC Hook was conducted in accordance with the following standards: ISO 10993:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and FDA Blue Book Memorandum #G95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The device passed the following tests:

- ISO Cytotoxicity
- ISO Sensitization
- ISO Intracutaneous Reactivity
- ISO Acute System Toxicity

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the HARMONIC Hook device; the system complies with IEC 60601-1-2:2007 for electromagnetic compatibility and IEC 60601-1:2005 for electrical safety.

Bench Testing

Blade amplitude and frequency were evaluated for HARMONIC Hook to support substantial equivalence to the predicate device. The maximum and minimum values, standard deviation and the mean were recorded for both blade frequency and amplitude. Data generated from this evaluation met the predetermined acceptance criteria.

Acute Animal Testing

Testing was performed in an acute study with the HARMONIC Hook vs. the predicate device to demonstrate that the tissue effects were not different than the predicate device. The results of the study demonstrated the ability of the subject device (HARBH32) to create tissue planes, dissect tissue, and provide hemostasis in different tissue types.

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 Hook is as safe and effective and performs as well as the identified legally marketed predicate device for cutting and coagulating soft tissue and sealing vessels up to 2 mm in diameter, as measured *in situ*.