



Food and Drug Administration
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July 10, 2015

Ethicon Endo-Surgery, LLC
Mr. Brian Godwin
Ethicon Endo-Surgery Incorporated
4545 Creek Road
Cincinnati, Ohio 45242

Re: K151340

Trade/Device Name: HARMONIC FOCUS[®] Long Shears + Adaptive Tissue Technology
Regulatory Class: Unclassified
Product Code: LFL
Dated: June 23, 2015
Received: June 24, 2015

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" (21CFR 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 -S

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

Indications for Use

510(k) Number (if known)

K151340

Device Name

HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology

Indications for Use (Describe)

The HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology are 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, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Company Ethicon Endo-Surgery, LLC
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Date Prepared 15 May 2015

Device Name

Trade Name: HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology
Common Name: Instrument, Ultrasonic Surgical
Model Number: HAR17F

Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code LFL)

Predicate Device

HARMONIC FOCUS® Shears + Adaptive Tissue Technology, cleared under K133314 on 03 December 2013

Device Description

The HARMONIC FOCUS+ Long Shears is a sterile, single patient use instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument has a curved blade and clamp arm with teflon pad. Measured from the blade tip to the MAX hand control power button, the instrument is 17 cm in length with a 16 mm active blade length. The HARMONIC FOCUS+ Long Shears instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

Indications for Use

The HARMONIC FOCUS Long Shears + Adaptive Tissue Technology are 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, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Technological Characteristics

The subject and predicate devices use the same ultrasonic technology to perform their intended use. Both devices use the HPBLUE handpiece to convert electrical energy into ultrasonic vibration.

The ergonomic differences between the subject and predicate devices are attributable to the respective design of each. Additionally, the subtle difference in the blade frequency upper bound is due to the increased blade length and has no clinical relevance with regards to tissue effect. These differences were found to not affect safety or effectiveness via design verification activities.

Performance Data

Ex-vivo tests were performed to ensure that the subject device performs as intended and meet design specifications. Device performance was assessed against the design requirements, and included process verification, design verification, and design validation.

Clinical Studies

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

Conclusion

This modification of the predicate device revealed no new issues of safety or efficacy as demonstrated through design validation and verification studies. The HARMONIC Focus Long Shears + Adaptive Tissue Technology are as safe and effective and perform as well as the identified legally marketed predicate devices for cutting and coagulating soft tissue and sealing vessels up to 5 mm in diameter, as measured *in situ*.