

510(k) Summary

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

Contact Brian Godwin, RAC
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OCT 17 2013

Date Prepared 20 August 2013

Device Name

Trade Name: HARMONIC ACE+ Shears with Advanced Hemostasis
Common Name: Instrument, Ultrasonic Surgical

Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code LFL)

Predicate Device

- HARMONIC ACE[®] Shears + Adaptive Tissue Technology, cleared under K120729 on 17 May 2012
- ENSEAL[®] G2 Tissue Sealers, cleared under K112033 on 08 Nov 2011

Device Description

The Ethicon Endo-Surgery HARMONIC ACE+ Shears with Advanced Hemostasis are used for coagulation and mechanical transection of soft tissue during laparoscopic and open procedures. The devices allow the surgeon to grasp, coagulate, and transect soft tissue with a single instrument. The devices are hand-actuated with a shaft and tissue effector that can be rotated. The energy delivery can be activated with hand activation or with an optional generator foot switch.

Indications for Use

The HARMONIC ACE+ with Advanced Hemostasis are 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 Advanced Hemostasis hand control button.

Technological Characteristics

The Ethicon Endo-Surgery HARMONIC ACE+ Shears with Advanced Hemostasis incorporate the same technological characteristics as that of the ultrasonic predicate device, HARMONIC ACE Shears + Adaptive Tissue Technology. The subject 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 ACE+ Shears with Advanced Hemostasis. The devices have an ergonomic grip housing assembly with hand control buttons (MIN for minimum power level, MAX for maximum power level, and Advanced Hemostasis for large vessel [up to 7 mm] sealing).

Adaptive Tissue Technology refers to the power output algorithm that is utilized by the devices. During use, the Adaptive Tissue Technology algorithm parameters stored on the device EEPROM are read by the generator and used to reduce the power (current) to the instrument and provide a secondary, higher pitched generator activation tone as Adaptive Tissue Technology regulates the delivery of energy. To do this the generator monitors the thermal condition of the blade during device activation. The Advanced Hemostasis mode utilizes a unique algorithm within Adaptive Tissue Technology that modulates the power delivery from the Generator G11 to the blade of the device maximizing hemostasis.

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 ACE+ Shears with Advanced Hemostasis perform as intended.

Conclusion

The results of the bench testing and laboratory evaluations in an animal model demonstrate that the HARMONIC ACE+ Shears with Advanced Hemostasis 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 7 mm in diameter, as measured in situ.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

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

October 17, 2013

Re: K132612

Trade/Device Name: HARMONIC ACE* + Shears with Advanced Hemostasis
Regulatory Class: Unclassified
Product Code: LFL
Dated: August 29, 2013
Received: August 30, 2013

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Neil R Ogden

2013.10.17 09:22:43 -04'00'

For Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132612

Device Name:

HARMONIC ACE[®]+ Shears with Advanced Hemostasis

Indications for Use:

The HARMONIC ACE[®]+ Shears with Advanced Hemostasis are 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 Advanced Hemostasis hand control button.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen

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Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Long H. Chen -A,
0.9.2342.19200300.100.1.1=1300369056
Date: 2013.10.16 15:22:24 -0400

For MXM

(Division Sign-off)

Division of Surgical Devices

510(k) Number K132612