510(k) Summary

DEC 1 6 2013

Company Information	Ethicon Endo-Surgery, LLC 4545 Creek Road Cincinnati, OH 45242
Contact Information	David M. Locke Regulatory Affairs Associate, Energy Ethicon Endo-Surgery (419) 233 – 2611 ext. 1281 dlocke1@its.jnj.com
Date Prepared	August 07, 2013
Device Name	Trade Names: HARMONIC ACE Curved Shears with Ergonomic Handle Classification Name: Instrument, Ultrasonic Surgical Common Name: Ultrasonic scalpel
Device Class	Unclassified
Panel	General & Plastic Surgery
Product Code	LFL
Classification Regulation	Unclassified

Predicate Device Information

The Predicate device is:

HARMONIC ACE Curved Shears with Pistol Handle and Hand Control (23 & 36cm length) cleared under K051036 & K060245

Device Description

The Harmonic ACE Curved Shear with Ergonomic Handle (ACE45E), Hand Control is a sterile, single patient use, ultrasonic surgical instrument consisting of an ergonomic housing assembly with hand control buttons, a rotating shaft with curved, ultrasonic blades and clamp arms. The handle housing has an integrated audible/tactile mechanism for indicating full closure. The instrument is designed for use in open or laparoscopic procedures and is available in the 45 centimeter shaft length. The Harmonic ACE instrument is used for the coagulation of vessels up to and including 5 mm in diameter.

Description of Changes to the Device

There have been minor design and labeling changes to the ACE45E Harmonic instrument since the clearance of K051036 and K060245 respectively. None of these changes required notification to the agency per FDA guidance document: *Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1).* These changes are being incorporated in this submission to provide the Agency with information for the most current version of these devices.

The Harmonic ACE45E Shear incorporates a more ergonomic design with activation buttons positioned in a more accessible location than the predicate pistol grip device. Minor design changes for manufacturability and user ease of assembly are also included. The ACE45E device is offered in a 45cm length. Changes were verified and validated in accordance with design control requirements. Labeling for the ACE45E Shear was updated to show the device with the ergonomic handle and to enhance warnings and precautions. There has been no change in intended use.

Intended Use	The Harmonic Shears 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, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space), and other open and endoscopic procedures.
Completion of Design Control Activities	The Ethicon Endo-Surgery design control procedures were followed to develop and test the minor modifications. The device continues to meet predetermined acceptance criteria. Design verification and validation testing revealed no new issues of safety and efficacy related to the changes.
Performance Data	Preclinical porcine vessel sealing validation studies demonstrated equivalent performance following handle and shaft modifications. Preclinical study criteria for success included the following parameters: transection times, hemostasis , thermal spread measurements and blood pressure challenges on sealed vessels. Additionally, functionality and reliability testing was performed to demonstrate that the subject device meets design requirements following device modifications. No clinical studies were required to support a finding of substantial equivalence. In conclusion, the testing results demonstrate that the ACE45E is as safe and effective as the predicate devices. The results from testing support the substantial equivalence of the ACE45E to the predicate devices.
Substantial Equivalence	The modified device is substantially equivalent to the unmodified predicate device in that it has the same intended use as the predicate device and the same technological characteristics that do not raise different types of questions of safety and effectiveness. The modification to a longer shaft does not adversely affect the hemostatic capability of the device. Testing shows the modified Harmonic instrument seals vessels up to and including 5 mm as did the unmodified Harmonic device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
Mr. David Locke
Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242

December 16, 2013

Re: K132522
Trade/Device Name: HARMONIC ACE Curved Shear with Ergonomic Handle
Regulatory Class: Unclassified
Product Code: LFL
Dated: October 21, 2013
Received: October 22, 2013

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 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. 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 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For 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): K132522

Device Names:

- HARMONIC ACE Curved Shear with Ergonomic Handle

Indications for Use:

The Harmonic Shears 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, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space), and other open and endoscopic procedures.

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 -A

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: 2013.12.16 10:10:03 -05'00'

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K132522