K063192

510(k) Summary

Company Ethicon Endo-Surgery, LLC
Angora Industrial Park, Building G
Caguas, Puerto Rico 00725

Contact Elizabeth Miller
Regulatory Affairs Associate II
Ethicon Endo-Surgery, Inc.
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Date Prepared October 19, 2006

Device Name Trade Name: HARMONIC FOCUS™ Curved Shears and Blue Hand Piece
Common or Usual Name: Instrument, Ultrasonic Surgical
Classification Name: Electrosurgical Cutting and Coagulation Device [21 CFR 878.4400 (LFL)]

Predicate Device HARMONIC Scalpel Shears and Hand Piece

Device Description The HARMONIC FOCUS™ Curved Shears are 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. The instruments working length is 9cm with a 16mm active blade length. The FOCUS instrument allows for the cutting and coagulation of vessels up to and including 5mm in diameter.

The HARMONIC Blue Hand Piece is designed to convert electrical energy from the HARMONIC Generator to mechanical motion for the instrument blade. The Blue Hand Piece is intended for use exclusively with the HARMONIC Scalpel Generator 300 (Model GEN04). The Blue Hand Piece is permanently attached to a blue cord, which connects to the front of the Generator.

Indications for Use The HARMONIC FOCUS™ Curved Shears 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, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

The HARMONIC Blue Hand Piece, when used in conjunction with the HARMONIC Scalpel 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.

Technological Characteristics The HARMONIC FOCUS™ Curved Shears with Hand Control is similar to the design and function of the predicate device, the HARMONIC ACE™ Curved Shears with Scissor Handle and Hand Control and the Ultracision Curved LCS/CS Shears.

The HARMONIC Blue Hand Piece is similar to the design of the predicate device, the HARMONIC Scalpel Hand Piece.

Performance Data Bench and preclinical testing was performed to evaluate the performance of the intended use of the new device. The testing shows that the HARMONIC FOCUS™ Curved Shears and the HARMONIC Blue Hand Piece is equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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% Ethicon Endo-Surgery, Inc., S.A.
Elizabeth Miller, RAC
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Cincinnati, Ohio 45242-2839

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Re: K063192
Trade/Device Name: HARMONIC FOCUS™ Shears and Blue Hand Piece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: LFL
Dated: January 12, 2007
Received: January 26, 2007

Dear Ms. Miller:

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.

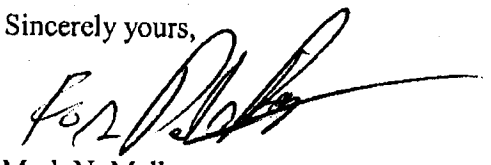
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063192

Device Name: **HARMONIC FOCUS™ Shears and Blue Hand Piece**

Indications for Use:

The HARMONIC FOCUS™ Shears 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, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063092

(Posted November 13, 2003)