

APR 7 2006

510(k) Summary

Company Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

Contact Elizabeth Miller
Regulatory Affairs Associate II
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Date Prepared January 30, 2006

Device Name Trade Name: Harmonic Scalpel Blades and Shears
Common or Usual Name: Instrument, Ultrasonic Surgical
Classification Name: Electrosurgical Cutting and Coagulation Device
[21 CFR 878.4400 (LFL)]

Predicate Device Harmonic Scalpel Blades and Shears

Device Description The Harmonic Scalpel Blades and Shears are ultrasonic surgical instruments for the cutting and coagulation of soft tissue incisions when bleeding control and minimal thermal injury are desired. The device system has three essential parts: the generator/ footswitch, the hand piece and the instruments, which are available in various lengths shapes and types. The selection of the appropriate instrument is a matter of surgeon preference.

Indications for Use The Harmonic 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 and endoscopic procedures.

The Harmonic Scalpel 5mm Instruments with Protective Sleeve 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 in general, plastic, gynecologic, *exposure to orthopedic structures (such as spine and joint space)*, ENT (Ears, Nose, Throat), including tissues of the soft palate, oral structures, and oropharyngeal airway, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

The Harmonic Scalpel 10cm Sharp Curved Blade Instruments 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, gynecologic, *exposure to orthopedic structures (such as spine and joint space)* and thoracic surgery.

The Harmonic Scalpel 10cm Curved Blade Instrument is intended to cut and coagulate soft tissue. It is to be used 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)*, ENT (Ears, Nose, Throat) and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

The Harmonic Scalpel 5 mm Instruments 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, *exposure to orthopedic structures (such as spine and joint space)*, plastic, gynecologic, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

The Harmonic Scalpel 10 mm LaparoSonic Instruments 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, gynecologic, and *exposure to orthopedic structures (such as spine and joint space)*.

Technological Characteristics The Harmonic Scalpel Blades and Shears technological characteristics are the same as the predicate device. No changes (materials construction, specifications, manufacturing or sterilization processes) to the currently marketed device. The device differs only in the indications.

Performance Data A clinical literature search was performed to show the use of the devices in providing exposure to orthopedic structures such as the hip, knee, shoulder, and spine.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ethicon Endo-Surgery Inc.
c/o Ms. Elizabeth Miller
Regulatory Affairs Associate II
4545 Creek Road
Cincinnati, Ohio 45242

Re: K060245

Trade/Device Name: Harmonic Scalpel Blades and Shears
Regulatory Class: Unclassified
Product Code: LFL
Dated: January 30, 2006
Received: January 31, 2006

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.

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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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


fo

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): K060245

Device Name: **Harmonic Scalpel Blades and Shears**

Indications for Use:

The Harmonic 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 and endoscopic procedures.

The Harmonic Scalpel 5mm Instruments with Protective Sleeve 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 in general, plastic, gynecologic, *exposure to orthopedic structures (such as spine and joint space)*, ENT (Ears, Nose, Throat), including tissues of the soft palate, oral structures, and oropharyngeal airway, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

The Harmonic Scalpel 10cm Sharp Curved Blade Instruments 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, gynecologic, *exposure to orthopedic structures (such as spine and joint space)* and thoracic surgery.

The Harmonic Scalpel 10cm Curved Blade Instrument is intended to cut and coagulate soft tissue. It is to be used 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)*, ENT (Ears, Nose, Throat) and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

The Harmonic Scalpel 5 mm Instruments 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, *exposure to orthopedic structures (such as spine and joint space)*, plastic, gynecologic, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).

The Harmonic Scalpel 10 mm LaparoSonic Instruments 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, gynecologic, and *exposure to orthopedic structures (such as spine and joint space)*.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off) *Q.M.ell*
**Division of General, Restorative,
and Neurological Devices**

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