K091290

510(k) Summary

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

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OCT 29 2009

Date Prepared October 27, 2009

New Device Name
Trade Name: Ethicon Endo Surgery® Rotating Hook Knife
Common or Usual Name: Electrosurgical Hook Electrodes
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Product Code GEI)

Predicate Device
Ethicon Endo Surgery® Articulating Hook Knife (K082955)

Device Description The Ethicon Endo Surgery® (EES) Rotating Hook Knife is a monopolar electrosurgical instrument intended for cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures. The device consists of a flexible wire cable and hook knife electrode, which can be extended and rotated from the flexible outer shaft using two handle control knobs. When connected to an electrosurgical generator and activated, the hook knife delivers a monopolar electrical current to the surgical site. This device passes through endoscopes having a 2.8 mm or larger working channel. This device is supplied sterile for single-patient use.

Indications for Use The Rotating Hook Knife is a monopolar electrosurgical instrument intended for cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures.

Technological Characteristics The EES Rotating Hook Knife device is very similar to the EES Articulating Hook Knife (K082955). Both devices consist of an electrode, an elongated flexible wire shaft and a handle. The handle allows for the manipulation of the electrode via the control knobs. In both devices, the metal electrode tip is used to deliver monopolar energy to the surgical site. Both devices are designed to be connected to electrosurgical generators, and utilize RF monopolar energy for operation. The "L" hook shape of the electrode in the Rotating Hook Knife is the same as in the EES Articulating

Hook Knife. Both devices feature rotation of the electrode. The Rotating Hook Knife does not contain the articulating feature present in the Articulating Hook Knife.

Performance Data. Bench testing was performed to demonstrate that the EES device performs as intended. The patient contact portions of the device have been evaluated for biocompatibility and comply with the requirements of ISO 10993-1. The device was tested to demonstrate compliance with the following standards:

- Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- Medical Electrical Equipment - Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment, IEC 60601-2-2, 2006/07/01
- Medical Electrical Equipment - Part 2-18: Particular Requirements for the Safety of Endoscopic Equipment, IEC 60601-2-18, 1996/08/01
- Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility, IEC 60601-1-2 (2004)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, Inc.
% Ms. Glenda Marsh
QS/RA Project Manager
4545 Creek Road
Cincinnati, Ohio 45242

OCT 29 2009

Re: K091290
Trade Name: Ethicon Endo-Surgery® Rotating Hook Knife
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Class: II
Product Code: GEI
Dated: October 15, 2009
Received: October 19, 2009

Dear Ms. Marsh:

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 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" (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,

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Ethicon Endo Surgery® Rotating Hook Knife**

Indications for Use:

The Rotating Hook Knife is a monopolar electrosurgical instrument intended for cutting, dissecting and cauterizing soft tissue during endoscopic electrosurgical procedures.

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091290

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)

(Posted November 13, 2003)