K073288
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510(k) Summary

JUN 12 2008

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

Contact Glenda C Marsh
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Date Prepared November 19, 2007

New Device Name Trade Name: Ethicon Endo Surgery® Articulating Snare
Common or Usual Name: Snare, Flexible
Classification Name: Endoscopic electrosurgical unit and accessories (21 CFR 876.4300, Product Code FDI)

Predicate Devices Rotatable Snare (K992477)
Single-Use Polypectomy Snare (K941750)

Device Description The Ethicon Endo Surgery® Articulating Snare consists of a flexible wire cable and loop, which can be extended, rotated, articulated, and retracted from the flexible outer shaft using a three-finger actuator. It is passed through endoscopes having a 3.2 mm or larger working channels. When activated, the snare delivers a monopolar electrical current to cut and cauterize tissue within the loop. The device is supplied sterile for single-patient use.

Indications for Use The Articulating Snare is intended for the electrosurgical removal and cauterization of gastrointestinal tract polyps through an endoscope.

Technological Characteristics The EES device has similar technologic characteristics to the predicate devices in that it consists of a flexible wire cable and loop that is used to remove polyps utilizing monopolar RF energy under endoscopic visualization. In all devices, the operator can deploy and retract the snare by using three fingers. As in the predicate devices, the EES device features rotation of the end-effector by manipulation of a rotation knob. In addition, the EES device features articulation of the end-effector to provide the clinician with improved tissue targeting capability.

Performance Data. Bench testing was performed to demonstrate that the EES device performs as intended. The device materials 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:

- AAMI HF 18, 2001 : *Electrosurgical Devices*
- IEC/EN 60601-2-2, 2000 : *Particular Requirements for the Safety of Endoscopic Equipment*
- IEC/EN 60601-2-18, 1996 : *Particular Requirements for the Safety of High Frequency of Surgical Equipment*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 12 2008

Ms. Glenda Marsh
Senior Project Manager, Quality Systems & Regulatory Affairs
Ethicon Endo-Surgery, Incorporated
4545 Creek Road
CINCINNATI OH 45242

Re: K073288
Trade/Device Name: Ethicon Endo Surgery® Articulating Snare
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI
Dated: May 29, 2008
Received: May 29, 2008

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 (Premarket Approval), 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073288

Device Name: **Ethicon Endo Surgery® Articulating Snare**

Indications for Use:

The Articulating Snare is intended for the electrosurgical removal and cauterization of gastrointestinal tract polyps through an endoscope.

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)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073288