

K091289

JAN 1 5 2010

510(k) Summary

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

Contact Renee Rowe
Staff QS/RA Project Manager
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242
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Date Prepared April 27, 2009

New Device Name

Trade Name: Ethicon Endo Surgery® Flexible Bipolar Hemostasis Forceps
Common or Usual Name: Electrosurgical Forceps
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Product Code GEI)

Predicate Devices

Ethicon Endo-Surgery Multiple Clip Applier (K051950)
Erbe BiClamp Open and Laparoscopic Instruments (K033421)
Olympus Medical Electrosurgical Hemostatic Forceps Series (K062517)
Ethicon Non-Stick Bipolar Forceps (K973384)

Device Description The Ethicon Endo-Surgery® Flexible Bipolar Hemostasis Forceps is a sterile, single-use device intended for use in endoscopic procedures where fusion of vessels or tissue bundles is performed. The device can be used on vessels up to 3 mm and bundles as large as will fit in the jaws of the instrument. A vessel fusion is created by the application of bipolar electrosurgical RF energy (coagulation) to the vessels placed between the jaws of the instrument. The Ethicon Endo-Surgery® Flexible Bipolar Hemostasis Forceps sources RF energy from an electrosurgical generator. Specifically, the Ethicon Endo-Surgery® Flexible Bipolar Hemostasis Forceps are designed for use with an ERBE VIO 300 D Electrosurgical Generator (ESU) System. This device passes through endoscopes having a 3.7 mm or larger working channels.

Indications for Use The Ethicon Endo-Surgery® Flexible Bipolar Hemostasis Forceps are intended for use in endoscopic procedures where fusion of vessels or tissue bundles is performed. The device can be used on vessels up to 3 mm and bundles as large as will fit in the jaws of the instrument.

The Ethicon Endo-Surgery® Flexible Bipolar Hemostasis Forceps are designed for use with an ERBE VIO 300 D Electrosurgical Generator (ESU) System. It is not recommended for use with other manufacturer's generators.

Technological Characteristics: The Ethicon Endo-Surgery® Flexible Bipolar Hemostasis Forceps is designed for use with currently marketed therapeutic gastroscopes and colonoscopes. It requires a 3.7-mm working channel or port for deployment. The device has a flexible shaft with a distal tip consisting of a set of jaws housing the electrodes. The Flexible Bipolar Hemostasis Forceps' is used to create a vessel fusion by applying bipolar electrosurgical RF energy (coagulation) to the vessel placed between the jaws of the instrument. The jaws contain atraumatic "grooves" which enable the device to grasp and manipulate tissue during endoscopic procedures. At the proximal end is a handle assembly. The rotation knob on the handle assembly can be used to rotate the end effector/jaws to facilitate positioning on the vessel. The Ethicon Endo-Surgery® Flexible Bipolar Hemostasis Forceps is provided with an insulated cable assembly with a plug for use with the bipolar receptacle of the ERBE VIO Electrosurgical Generator.

Performance Data. Bench, animal, biocompatibility, and electrical testing was performed to demonstrate that the EES device performs as intended and is mentioned in later sections of the application.



Ethicon Endo-Surgery Inc.
% Ms. Renee Rowe
4545 Creek Drive
Cincinnati, Ohio 45242

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

JAN 15 2010

Re: K091259

Trade/Device Name: Ethicon Endo Surgery® Flexible Bipolar Hemostasis Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 9, 2009
Received: December 10, 2009

Dear Ms. Rowe:

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.

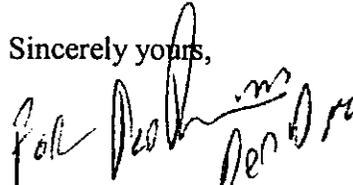
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with some initials and a date "10/1/02" visible.

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® Flexible Bipolar Hemostasis Forceps**

Indications for Use:

The Ethicon Endo-Surgery® Flexible Bipolar Hemostasis Forceps are intended for use in endoscopic procedures where fusion of vessels or tissue bundles is performed. The device can be used on vessels up to 3 mm and bundles as large as will fit in the jaws of the instrument.

The Ethicon Endo-Surgery® Flexible Bipolar Hemostasis Forceps are designed for use with an ERBE VIO 300 D Electrosurgical Generator (ESU) System. It is not recommended for use with other manufacturer's generators.

Prescription Use **X**
(Part 21 CFR 801 Subpart D)

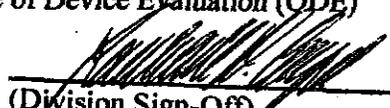
AND/OR

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)

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(Posted November 13, 2003)



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

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