



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
David Locke
Senior Regulatory Affairs Specialist
4545 Creek Road
Cincinnati, Ohio 45242

Re: K160128

Trade/Device Name: Endopath Electrosurgery Probe Plus II
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 19, 2016
Received: January 20, 2016

Dear David Locke:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160128

Device Name

ENDOPATH Electrosurgery Probe Plus II

Indications for Use (Describe)

Indications

The ENDOPATH Electrosurgery Probe Plus II system has application in minimally invasive procedures to facilitate tissue dissection, coagulation, irrigation, and fluid evacuation through a common trocar sleeve.

Contraindications

- These instruments are not intended for contraceptive coagulation of fallopian tissue but may be used to achieve hemostasis following transection of the fallopian tube.
- These instruments are not intended for use when minimally invasive techniques are contraindicated.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Company

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Date Prepared 19 January 2016

Device Name

Trade Name: Evacuation/Irrigation/Electrosurgical Device
Classification Name: Laparoscope, General & Plastic Surgery
Common Name: Endopath® Electrosurgery Probe Plus II
Catalog Number: EPH02, EPS01, EPS02, EPS03, EPS04, EPS05, EPS06, EPS07

Device Class

Class II

Device Panel

General & Plastic Surgery

Product Code

GEI

Predicate Device

Ethicon Evacuation/Irrigation/Electrosurgical Device cleared under K912492

Device Description

The Endopath® Electrosurgery Probe Plus II device (product codes beginning with EPH and EPS) work with a standard monopolar unit and has applications for minimally invasive procedures to facilitate tissue dissection, coagulation, irrigation, and fluid evacuation through a common trocar sleeve. The subject device system offers one handle (EPH02) and seven shafts (EPS01-EPS07) which allow for a variety of configurations to best meet the surgeon's needs. Shafts EPS01 through EPS07 are for use through a 5 mm diameter surgical trocar or a larger trocar with a 5 mm reducer.

Indications for Use

The ENDOPATH Electrosurgery Probe Plus II system has application in minimally invasive procedures to facilitate tissue dissection, coagulation, irrigation and fluid evacuation through a common trocar sleeve.

Contraindications

- These instruments are not intended for contraceptive coagulation of fallopian tissue but may be used to achieve hemostasis following transection of the fallopian tube.
- These instruments are not intended for use when minimally invasive techniques are contraindicated.

Technological Characteristics

The subject ENDOPATH Electrosurgery Probe Plus II device and predicate Ethicon Evacuation/Irrigation/Electrosurgical device use the same monopolar technology to perform their intended use. The subject and predicate devices also use the same standard suction and irrigation modalities to perform their intended use. The subject ENDOPATH Electrosurgery Probe Plus II device is similar to the predicate Ethicon Evacuation/Irrigation/Electrosurgical device with respect to the primary modes of action which include suction, irrigation and hemostasis. A few technological differences were identified between the subject device and the currently marketed predicate devices, attributable to the respective design of each. As compared with the predicate devices, the subject device does however incorporate several design enhancements which includes suction and irrigation button force improvement, monopolar activation force improvement, elimination of the button pin, improved ergonomics, and combined hand and foot activation capability (hand activation through the ENDOPATH Electrosurgery Probe Plus II device itself and foot activation through a monopolar electrosurgery unit (ESU) generator foot pedal).

Performance Data

Bench testing and laboratory evaluations were conducted to demonstrate that the ENDOPATH Electrosurgery Probe Plus II performed as intended.

Sterilization

The subject device and the predicate device are sterilized via gamma radiation; both devices are sterilized to the same sterility assurance level.

Biocompatibility

The biocompatibility evaluation for the ENDOPATH Electrosurgery Probe Plus II device was conducted in accordance with the following standards: ISO 10993:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and FDA Blue Book Memorandum #G95-1: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The device passed all biocompatibility ISO testing which included cytotoxicity, sensitization, intracutaneous reactivity and acute system toxicity testing.

EMC

Electrical safety and EMC testing were conducted on the ENDOPATH Electrosurgery Probe Plus II; the system complies with IEC 60601-1-2:2007 for electromagnetic compatibility and IEC 60601-1:2005 for electrical safety.

Bench

Flow rate of suction and irrigation, impedance, minimum distal retraction force and sheath extension force were evaluated for the ENDOPATH Electrosurgery Probe Plus II to support substantial equivalent to the predicate device. Data generated from these tests met the predetermined acceptance criteria.

Acute

Testing was performed in an acute study with the ENDOPATH Electrosurgery Probe Plus II vs. the currently marketed predicate device to demonstrate that the tissue effects were not different than the predicate device. The results of the study demonstrated the ability of the subject device to create tissue planes, dissect tissue, and provide hemostasis in different tissue types.

Clinical

This premarket notification does not rely on human clinical trial data to demonstrate substantial equivalence.

Conclusion

The results of the bench testing and laboratory evaluations in an animal model demonstrate that the Endopath® Electrosurgery Probe Plus II device is as safe and effective and performs as well as the identified legally marketed predicate device.