May 7, 2018

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

Re: K180031
Trade/Device Name: Endopath Electrosurgery Probe Plus II, Pencil Grip Handle
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 5, 2018
Received: April 6, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180031

Device Name
ENDOPATH Electrosurgery Probe Plus II (Pencil)

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

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Date Prepared January 2, 2018

Device Name
Trade Name: Evacuation/Irrigation/Electrosurgical Device
Classification Name: Laparoscope, General & Plastic Surgery
Common Name: Endopath® Electrosurgery Probe Plus II, Pencil Grip Handle
Catalog Number: EPH04

Device Class
Class II

Device Panel
General & Plastic Surgery

Product Code
GEI

Predicate Device
Endopath® Electrosurgery Probe Plus II cleared under K160128

Device Description
The Endopath® Electrosurgery Probe Plus II device with the pencil handle configuration (product code EPH04) works 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. Previously cleared shafts (K160128) EPS01 through EPS07 all attach to the EPH04 pencil handle in the same manner as the previously cleared pistol handle, and are for use through a 5mm diameter surgical trocar or a larger trocar with a 5mm 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 Pencil device (EPH04) and predicate ENDOPATH Electrosurgery Probe Plus II Pistol device (EPH02) 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 Pencil device is similar to the predicate ENDOPATH Electrosurgery Probe Plus II Pistol device with respect to the primary modes of action which include suction, irrigation and hemostasis. As compared with the predicate devices, the subject device takes on a straight pencil configuration as to where the cleared predicate device takes on a pistol configuration.

Performance Data
Bench testing was conducted to demonstrate that the ENDOPATH Electrosurgery Probe Plus II Pencil device (product code EPH04) 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
Biocompatibility was not required for this submission as no new materials were introduced on this device.

EMC
Electrical safety and EMC testing were conducted on the ENDOPATH Electrosurgery Probe Plus II Pencil device; the system complies with IEC 60601-1-2:2007 for electromagnetic compatibility and IEC IEC 60601-2-2:2009 & IEC 60601-1:2005+A1:2012 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 Pencil device to support substantial equivalent to the predicate device. Data generated from these tests met the predetermined acceptance criteria.

Animal
This premarket notification does not rely on preclinical animal testing to demonstrate substantial equivalence.

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

Conclusion
The results of the bench testing demonstrate that the Endopath® Electrosurgery Proble Plus II Pencil device (product code EPH04) is as safe and effective and performs as well as the identified legally marketed predicate device.