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

April 18, 2017

Ethicon Endo-Surgery, LLC
Ms. Rubina Dosani
Ethicon Endo-Surgery, LLC
4545 Creek Road
Cincinnati, Ohio 45242

Re: K163523
Trade/Device Name: ECHELON CIRCULAR Powered Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: March 20, 2017
Received: March 22, 2017

Dear Ms. Dosani:

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" (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 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,

David Krause -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163523

Device Name
ECHELON CIRCULAR™ Powered Staplers

Indications for Use *(Describe)*
The ECHELON CIRCULAR™ Powered Staplers have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter Information: Ethicon, LLC
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Date Prepared December 14, 2016

Device Trade Name:	ECHELON CIRCULAR™ Powered Staplers
Device Common Name:	Circular Stapler
Classification Regulation:	21 CFR 878.4750
Device Class:	II
Panel:	General & Plastic Surgery
Classification (Product) Code:	GDW
Legally Marketed Predicate Device:	Ethicon Endo-Surgery® Curved Intraluminal Staplers (cleared under K983536)

Device Description

The ECHELON CIRCULAR™ Powered Staplers are sterile, single-patient use devices that simultaneously staple and cut tissue with a battery powered firing system to create an anastomosis. The devices deliver 2 rows of staples on the outside of the cut line. The ECHELON CIRCULAR™ Powered Staplers are available in a 24 cm curved shaft length in 4 end-effector sizes: 23mm, 25mm, 29mm and 31mm. Each device has a detachable anvil that allows a surgeon to place the anvil in the desired location. The devices are packaged with a battery pack that must be installed prior to use.

Indications for Use

The ECHELON CIRCULAR™ Powered Staplers have applications throughout the alimentary tract for end-to-end, end-to side, and side-to-side anastomoses.

Technological Characteristics

The subject device utilizes battery power to allow powered staple formation and lumen cutting to create the anastomosis. The subject device has a similar design as the predicate with the addition of tighter staple height range and staple pockets extensions to the end-effector of the device as

well as a slightly different shape of the formed staples. Similar to the predicate, a rotatable adjustment knob enables the compression of tissue and selection of a target staple height based on the tissue compression within the green zone. No energy passes through to the patient in the use of the subject or predicate devices. Neither the subject device or predicate device uses software.

Performance Data

Performance data demonstrate that the subject device is substantially equivalent to the predicate device and the differences between the devices were found not to affect safety or performance. The following bench and animal tests were performed to demonstrate substantial equivalence to the predicate:

- staple line integrity and staple form quality equivalency
- leak onset pressure equivalency
- force to fire
- formed staple height
- battery output
- fluid ingress

Animal testing performed included acute hemostasis evaluation, device removal acceptability, device insertion tissue effects, healing of stapled anastomosis and staple line perfusion.

The conclusions of the testing demonstrate that the subject device performs substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness.

This submission does not include data from Clinical Studies.