July 27, 2020

Ethicon Endo-Surgery LLC
% Rubina Dosani
Manager, Regulatory Affairs
Ethicon Endo-Surgery, LLC
4545 Creek Road
Cincinnati, Ohio 45242

Re: K201280
Trade/Device Name: Ethicon Circular Stapler, Ethicon Circular Stapler -XL Sealed
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: May 9, 2020
Received: June 29, 2020

Dear Rubina 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K201280

Device Name
Ethicon™ Circular Stapler

Indications for Use *(Describe)*
The Ethicon™ Circular Staplers have application 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.

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510(k) Summary

Submitter Information: Ethicon Endo-Surgery, LLC
475 Calle Street
Guaynabo, PR 00969

Application Correspondent
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Manager, Regulatory Affairs
Ethicon Endo-Surgery, LLC.
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Date Prepared May 9, 2020

Device Trade Name:	Ethicon™ Circular Staplers, Ethicon™ Circular Staplers XL Sealed
Device Common Name:	Circular Stapler
Classification Regulation:	21 CFR 878.4750; Implantable Staple
Device Class:	II
Panel:	79, General & Plastic Surgery
Classification (Product) Code:	GDW
Legally Marketed Predicate Device:	Ethicon™ Circular Staplers, Ethicon™ Circular Staplers XL, (cleared under K181653)

Device Description

The Ethicon™ Circular Staplers are sterile, single use devices that simultaneously staple and cut tissue to create an anastomosis. The devices deliver 2 concentric rows of staples on the outside of the cut line. The Ethicon™ Circular Staplers are available in two device configurations: CDH and ECS and two shaft lengths; a standard 26 cm shaft and an XL 37 cm shaft. Each configuration is available in 4 endeffector sizes: 21 mm, 25 mm, 29 mm, 33 mm. These configurations function in the same manner - to compress tissue and to produce the same closed staple on tissue. Each device has a detachable anvil that allows a surgeon to place the anvil in the desired location.

Indications for Use

The Ethicon™ Circular Staplers have applications throughout the alimentary tract for end-to-end, end-to side, and side-to-side anastomoses. The predicate device also has the same indications for use. There is no change to the indications for use.

Technological Characteristics

The Ethicon™ Circular Stapler is substantially equivalent to the predicate Ethicon Endo-Surgery® Curved Intraluminal Staplers with respect to the device function and design. The subject device has a similar design as the predicate except for a change in the knife grind angle and the washer thickness in the end-effector of the device. 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. The device is manually powered; it is not powered by an outside energy source. Neither the subject device nor predicate device uses software.

Performance Data

Ex-vivo (bench) testing was performed to ensure that the device performed as intended and met design specifications. Device performance was assessed against the design requirements. Risk analysis and design verification testing were conducted for the changes described in this submission to ensure that the performance of the device was not affected by the device modifications. Verification testing included tissue cutting reliability testing, test skin force-to-fire, and device stapling performance testing. The results of the testing support the conclusion that the performance of the device has not been affected by the changes.

This submission does not include data from Clinical Studies.

Conclusion

The modification described in this submission does not affect the intended use of the device or alter the fundamental scientific technology of the device. Summary information from the design control process serves as the basis for this submission. The Ethicon™ Circular Stapler is substantially equivalent to the legally marketed predicate device based upon intended use, technological characteristics and performance testing.