May 11, 2026

Ethicon Endo- Surgery., LLC
Aysenur Erucman
Senior Regulatory Affairs Specialist
475 Calle C
Guaynabo, PR 00969

Re: K260196
Trade/Device Name: ETHICON™ Circular Stapler (CDH21mm); ETHICON™ Circular Stapler (CDH25mm); ETHICON™ Circular Stapler (CDH29mm); ETHICON™ Circular Stapler (CDH33mm); ETHICON™ Circular Stapler - XL Sealed (ECS21mm); ETHICON™ Circular Stapler - XL Sealed (ECS25mm); ETHICON™ Circular Stapler - XL Sealed (ECS29mm); ETHICON™ Circular Stapler - XL Sealed (ECS33mm)
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: January 22, 2026
Received: January 22, 2026

Dear Aysenur Erucman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260196

Device Name
ETHICON™ Circular Stapler (CDH21mm, CDH25mm, CDH29mm, CDH33mm)
ETHICON™ Circular Stapler-XL Sealed (ECS21mm, ECS25mm, ECS29mm,ECS33mm)

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K260196

I. SUBMITTER

Company: ETHICON Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact: Aysenur Huseyinoglu Erucman
Senior Regulatory Affairs Specialist
ETHICON Endo-Surgery, Inc.
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Date Prepared: April 22, 2026

II. SUBJECT DEVICES

Trade Names:

ETHICON™ Circular Stapler CDH 21mm
ETHICON™ Circular Stapler CDH 25mm
ETHICON™ Circular Stapler CDH 29mm
ETHICON™ Circular Stapler CDH 33mm
ETHICON™ Circular Stapler-XL Sealed ECS 21mm
ETHICON™ Circular Stapler-XL Sealed ECS 25mm
ETHICON™ Circular Stapler-XL Sealed ECS 29mm
ETHICON™ Circular Stapler-XL Sealed ECS 33mm

Common or Usual Name: Surgical Stapler with Implantable Staples
Classification Name: Implantable staple (21 CFR 878.4750)
Regulatory Class: Class 2 -Staple, Implantable
Product Code: GDW

III. PREDICATE DEVICE

Predicate Device 510(k) Number	Predicate Device Name	Predicate Device Model Numbers
K201280	ETHICON™ Circular Stapler – ETHICON™ XL Circular Stapler	CDH21mm, CDH25mm, CDH29mm, CDH33mm, ECS21mm, ECS25mm, ECS29mm, ECS33mm

IV. REFERENCE DEVICE

Reference Device 510(k) Number	Reference Device Name	Reference Device Model Numbers
K163523	ECHELON CIRCULAR™ Powered Staplers	CDH21P,CDH25P, CDH29P, CDH33P, ECS21, ECS25P, CS29P,ECS33P

V. DEVICE DESCRIPTION

The ETHICON™ Circular Staplers are sterile, single-use surgical instruments designed to simultaneously staple and cut tissue to create an anastomosis. Each device delivers two concentric rows of staples on either side of the cut line and includes a detachable anvil to facilitate placement. The staplers are available in two configurations (CDH and ECS), two shaft lengths (26 cm standard and 37 cm XL), and four end-effector sizes (21 mm, 25 mm, 29 mm, and 33 mm). All configurations function identically in terms of tissue compression and staple formation, differing primarily in shaft length and pneumatic sealing features for laparoscopic use.

VI. INDICATIONS FOR USE

ETHICON CIRCULAR Staplers have application throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Subject and Predicate Device are sterile, single-use, mechanical stapling devices designed to simultaneously cut and staple tissue to create an anastomosis in the alimentary tract. They share identical end-effector designs, staple configurations, device sizes, ergonomic features, packaging, and sterilization methods.

Characteristic	Subject Device- ETHICON™ Circular Stapler – ETHICON™ XL Circular Stapler	Predicate Device (K201280)	Reference Device (K163523)
Indication for Use	The ETHICON™ Circular Staplers have application throughout the alimentary tract for end-to-end, end-to side, and side-to-side anastomoses.	Same.	Same. The ECHELON CIRCULAR™ Powered Staplers have application throughout the alimentary tract for end-to-end, end-to-side, and side-to-side Anastomoses.
Intended Use	Creation of anastomoses.	Same.	Same.
Contraindications	Do not use where the combined tissue thickness cannot be comfortably compressed to the closed staple height (Refer to the ETHICON™ Circular Stapler Product Code Table below) or where the internal diameter of the structure is less than 21 mm. If the device is used on tissue that cannot comfortably compress to the closed staple height, or can easily compress to less than the closed staple height, an inadequate anastomosis could be formed resulting in leakage, inadequate hemostasis, or improper healing.	Same.	Tissue thickness should be carefully evaluated before firing any stapler. Do not use where the combined tissue thickness cannot be comfortably compressed to the selected closed staple height, or too easily compresses to less than the selected closed staple height (Refer to the ECHELON CIRCULAR™ Powered Stapler Product Codes Table below for range of adjustable closed staple height) or where the internal diameter of the structure is less than 23 mm. If the device is used on tissue that cannot be comfortably compressed to the selected closed staple height, or too easily compresses to less than the selected closed staple height, an inadequate anastomosis could be formed resulting in leakage, inadequate hemostasis, or improper healing.
Sterile, Single Patient Use	Yes	Same.	Same.
Functional Use	Simultaneously transect and staple tissue	Same.	Same.
Biocompatibility of Materials	All tissue-contacting materials comply with ISO 10993-1.	Same.	Same.

Characteristic	Subject Device- ETHICON™ Circular Stapler – ETHICON™ XL Circular Stapler	Predicate Device (K201280)	Reference Device (K163523)
Packaging Method	Packaged in a clear PETG blister with a heat sealed preprinted Tyvek Lid.	Same.	Same.
Device Operation	Mechanical (hand) power used to staple and cut while creating an anastomosis closure.	Same.	Battery power used to staple and cut while creating an anastomosis closure
Sterilization Method	Gamma Radiation	Same.	EO sterilization
Shelf Life	5 years	Same.	3 years

The key technological differences pertain to the knife component. The Subject Device incorporates a knife made from UNS SS304 stainless steel, replacing the UNS SS305 stainless steel used in the predicate device. Additionally, the knife edge in the subject device is formed using Electrochemical Machining (ECM)—a non-contact precision process that provides improved edge consistency and dimensional control. In contrast, the predicate device knife was manufactured through conventional grinding and buffing techniques.

VIII. PERFORMANCE DATA:

The following performance data demonstrate that the Subject Device is substantially equivalent to the Predicate Device. The modifications made to the knife component were shown not to impact the safety, effectiveness, or overall performance of the device.

Bench Testing

- Force to Fire
- Washer & Test Skin Full Cut
- Thin Tissue Full Cut
- Design Thickness Tissue Full Cut
- Fully cut indicated tissue and Crossing Staples

Animal Testing: Animal testing was not required for this submission, as substantial equivalence was demonstrated through non-clinical performance testing.

Clinical studies: Clinical studies were not required for this submission.

Biocompatibility: Studies were performed and confirmed that the Subject Device is biocompatible for the intended patient contact. No new risks were introduced as a result of the material change. All tissue contacting materials comply with ISO 10993-1.
Electrical Safety and Electromagnetic Compatibility: The device is not powered and therefore this does not apply.

IX. CONCLUSIONS

In conclusion, Design verification testing confirmed that did not introduce new issues of safety and effectiveness. The changes do not introduce a new indication for use or change the intended use, and the Subject Device is substantially equivalent to the Predicate Device.