October 28, 2024

Ethicon Endo-Surgery, LLC
Megan Westendorf
Regulatory Affairs Specialist
475 Calle C
Guaynabo, PR 00969

Re: K241630
Trade/Device Name: ECHELON 4000 60mm Compact Stapler (EC3D60C); ECHELON 4000 60mm Standard Stapler (EC3D60S); ECHELON 4000 60mm Long Stapler (EC3D60L); ECHELON 3D 60mm White Reload (ER60W); ECHELON 3D 60mm Blue Reload (ER60B); ECHELON 3D 60mm Green Reload (ER60G); ECHELON 3D 60mm Black Reload (ER60T)
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: September 24, 2024
Received: September 24, 2024

Dear Megan Westendorf:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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

Digitally signed by Tek N. Lamichhane -S
Date: 2024.10.28 17:24:10 -04'00'

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.

Submission Number *(if known)*

K241630

Device Name

ETHICON 4000 60mm Compact Stapler (EC3D60C);
ETHICON 4000 60mm Standard Stapler (EC3D60S);
ETHICON 4000 60mm Long Stapler (EC3D60L);
ETHICON 3D 60mm White Reload (ER60W);
ETHICON 3D 60mm Blue Reload (ER60B);
ETHICON 3D 60mm Green Reload (ER60G);
ETHICON 3D 60mm Black Reload (ER60T)

Indications for Use *(Describe)*

The ETHICON™ 4000 Staplers and ETHICON™ 3D Reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue reinforcement materials.

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
K246130

I. SUBMITTER

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

Contact: Megan Westendorf
Senior Regulatory Affairs Specialist
Ethicon Endo-Surgery, Inc.
Phone: 513-479-6951
Email: mwestend@its.jnj.com

Date Prepared: October 25, 2024

II. Subject DEVICES

Trade Names:	**Product Codes:**
ETHICON™ 4000 60mm Compact Stapler	EC3D60C
ETHICON™ 4000 60mm Standard Stapler	EC3D60S
ETHICON™ 4000 60mm Long Stapler	EC3D60L
ETHICON™ 3D 60mm White Reload	ER60W
ETHICON™ 3D 60mm Blue Reload	ER60B
ETHICON™ 3D 60mm Green Reload	ER60G
ETHICON™ 3D 60mm Black Reload	ER60T

Classification Name: Surgical Stapler
Staple, Implantable
Classification Regulation: 21 CFR 878.4740
21 CFR 878.4750
Device Class: II
Product Code: GDW, GAG

III. Predicate DEVICES

Predicate Device 510(k) Number	Predicate Device Name	Predicate Device Product Codes
K213633	ECHELON™ 3000 60mm Stapler	ECH60C, ECH60S, ECH60L
K183435	ECHELON Endoscopic Linear Cutter Reload (+Gripping Surface Technology) 60mm	GST60W, GST60B, GST60G, GST60T

Reference DEVICES

Reference Device 510(k) Number	Reference Device Name	Reference Device Product Codes
K223760	ECHELON LINEAR™ Cutter Reloads	GLCR60B, GLCR60G, GLCR80B, GLCR80G, GLCR100B, GLCR100G
K200420	ECHELON CONTOUR™ Curved Cutter Reloads	GCR40B, GCR40G
K163523	ECHELON CIRCULAR™ Powered Stapler	CDH23P, CDH25P, CDH29P, CDH31P

IV. Device Description

The ETHICON™ 4000 Stapler and ETHICON™ 3D Reloads are intended for transection, resection and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue reinforcement materials.

The ETHICON™ 4000 Stapler and ETHICON™ 3D Reloads are sterile, single-patient-use instruments that simultaneously cut and staple tissue. There are six staggered rows of staples, three on either side of the cut line. Together, the ETHICON™ 4000 60 mm Staplers and ETHICON™ 3D Reloads deliver 3D staples in the first, second, fifth and sixth rows of staples. The third and fourth rows (nearest the knife) maintain the traditional 2D B-formed staples.

ETHICON™ 4000 60 mm Staplers have a staple line that is approximately 60 mm long and a cut line that is approximately 57 mm long. The Subject stapler device is available in three different shaft lengths - Compact, Standard and Long. The shaft can rotate freely in both directions and an articulation mechanism enables the distal portion of the shaft to pivot to facilitate lateral access to the operative site. The device is packaged with a primary lithium Battery Pack that must be installed prior to use. There is embedded software to articulate and initiate firing of the device.

The instruments are packaged without a reload and must be loaded prior to use. The instrument may be reloaded for a maximum of 12 firings during a single procedure. A Staple Retaining Cap on the reload protects the staple leg points during shipping and transportation. The instruments' lockout feature is designed to prevent a used or improperly installed reload from being re-fired or an instrument from being fired without a reload.

The staples are permanent implants that provide tissue closure and apposition from the time of implant through the critical phases of healing. The staples remain in place for the patient's lifetime, unless in the opinion of the treating physician, they require removal.

The Subject stapler and reloads will not be compatible with previous ECHELON™ staplers and reloads. This is a new platform that will work with 3D reloads only.

V. Intended Use/Indications for Use

The ETHICON™ 4000 Staplers and ETHICON™ 3D Reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue reinforcement materials.

VI. Technological Comparison

Characteristic	**Subject Device** Staplers: EC3D60C, EC3D60S, EC3D60L Reloads: ER60W, ER60B, ER60G, ER60T	**Predicate Device** Staplers: ECH60C, ECH60S, ECH60L Reloads: GST60W, GST60B, GST60G, GST60T
Indication for Use	The ETHICON™ 4000 Staplers and ETHICON™ 3D Reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have applications in multiple open or minimally invasive general, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue reinforcement materials.	The ECHELON FLEX™ and ECHELON™ 3000 families of staplers and reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue reinforcement materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney, and spleen.
Intended Use	Same	Same
Contraindications	Same	Same

Characteristic	Subject Device Staplers: EC3D60C, EC3D60S, EC3D60L Reloads: ER60W, ER60B, ER60G, ER60T	Predicate Device Staplers: ECH60C, ECH60S, ECH60L Reloads: GST60W, GST60B, GST60G, GST60T
Sterile, Single Patient Use	Yes	Same
Sterilization Method	Same	Same
Control Mechanism	Same	Same
Shelf Life	Same	Same
Biocompatibility of Materials	Meets ISO 10993-1	Same
Packaging Materials	Same	Same
Stapler Anvil & End Effector	Compatible with ETHICON 3D Reloads only	Compatible with ETHICON 2D reloads
Staple Form	3D staple form (first, second, fifth and sixth rows) 2D staple form (third & fourth rows)	2D staple form (all rows)
Staple Material	Titanium Alloy	Same
Staple Line Length	60 mm	Same
Formed Staple Height in Tissue	Same	Same
Staple Rows	6	Same

The reference devices demonstrate the same 3D staple design as the Subject device and similar intended use. The same stapling performance tests were conducted on the Subject and reference devices, and all met their respective acceptance criteria. The equivalent staple design characteristics and successful completion of the same stapling performance tests demonstrate safe and effective staple formation with the 3D staple design.

VII. Non-Clinical and/or Clinical Tests Summary

Non-Clinical Studies

The nonclinical tests that have been submitted include staple performance equivalence bench testing compared to the predicate; device functional performance bench testing; staple line strength product characterization of Subject and Predicate devices; and the Human Factors testing report. Biocompatibility evaluation was performed according to ISO 10993-1. Pre-clinical data including Hemostasis Performance and Tissue healing response in Abdominal and Thoracic procedures.

Clinical Studies

The premarket submission did not rely on the assessment of clinical performance data to demonstrate device performance and equivalence.

VIII. Conclusion

In all cases the subject devices demonstrated either equivalent or improved performance to the predicate devices or passed the functional requirements of the subject device features. The ETHICON™ 4000 and ETHICON™ 3D Reloads therefore meet the acceptance criteria for bench testing and have been demonstrated to be safe and effective.

In conclusion, the performance testing demonstrates that the Subject device performs substantially equivalent to the Predicate devices and does not raise any new questions of safety and effectiveness.