December 17, 2025

Ethicon Endo-Surgery, LLC
Heidi Calderon
Senior Regulatory Affairs Program Lead
475 Calle C
Guaynabo, PR 00969

Re: K252739
Trade/Device Name: ETHICON™ 4000 45mm Compact Stapler (EC3DT45C); ETHICON™ 4000 45mm Standard Stapler (EC3DT45S); ETHICON™ 4000 45mm Long Stapler (EC3DT45L); ETHICON™ 3D 45mm White Reload (ER45W); ETHICON™ 3D 45mm Blue Reload (ER45B); ETHICON™ 3D 45mm Green Reload (ER45G); ETHICON™ 3D 45mm Black Reload (ER45T)

Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: August 27, 2025
Received: August 28, 2025

Dear Heidi Calderon:

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

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252739

Please provide the device trade name(s).

ETHICON™ 4000 45mm Compact Stapler (EC3DT45C);
ETHICON™ 4000 45mm Standard Stapler (EC3DT45S);
ETHICON™ 4000 45mm Long Stapler (EC3DT45L);
ETHICON™ 3D 45mm White Reload (ER45W);
ETHICON™ 3D 45mm Blue Reload (ER45B);
ETHICON™ 3D 45mm Green Reload (ER45G);
ETHICON™ 3D 45mm Black Reload (ER45T)

Please provide your Indications for Use below.

The ETHICON™ 4000 45mm Staplers and ETHICON™ 3D 45mm 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 instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney, and spleen.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
(K252739)

I. SUBMITTER

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

Contact: Heidi Calderon
Senior Regulatory Affairs Program Lead
Ethicon Endo-Surgery, Inc.
Phone: 939-644-8198
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Date Prepared: August 27, 2025

II. Subject Devices

Trade Names:	**Product Models:**
ETHICON™ 4000 45mm Compact Stapler	EC3DT45C
ETHICON™ 4000 45mm Standard Stapler	EC3DT45S
ETHICON™ 4000 45mm Long Stapler	EC3DT45L
ETHICON™ 3D 45mm White Reload	ER45W
ETHICON™ 3D 45mm Blue Reload	ER45B
ETHICON™ 3D 45mm Green Reload	ER45G
ETHICON™ 3D 45mm Black Reload	ER45T

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 Device

Predicate Device 510(k) Number	Predicate Device Name	Predicate Device Product Models
K250835	ETHICON™ 4000 60mm Stapler	EC3D60C, EC3D60S, EC3D60L
K250835	ETHICON™ 3D 60mm Reloads	ER60W, ER60B, ER60G, ER60T

IV. Reference Devices

Reference Device 510(k) Number	Reference Device Name	Reference Device Product Models	Reference Device Purpose
K241630	ETHICON™ 4000 60mm Stapler	EC3D60C, EC3D60S, EC3D60L	Performance Testing and technological characteristics
K241630	ETHICON™ 3D 60mm Reloads	ER60W, ER60B, ER60G, ER60T	Performance Testing and technological characteristics
K183435	ECHELON Endoscopic Linear Cutter Reload (+Gripping Surface Technology) 60mm	GST60W, GST60B, GST60G, GST60T	Performance Testing and technological characteristics

V. Device Description

The ETHICON™ 4000 45mm Stapler and ETHICON™ 3D Reloads are intended for transection, resection and/or creation of anastomoses.

The ETHICON™ 4000 45mm Stapler and ETHICON™ 3D 45mm 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 45mm Staplers and ETHICON™ 3D 45mm 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 45mm Staplers have a staple line that is approximately 45 mm long and a cut line that is approximately 42 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 end effector has a mechanism that enables the distal portion of the anvil to toggle between the straight and curved configurations. 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 staplers are packaged without a reload and must be loaded prior to use. The stapler 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 staplers' 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.

VI. Intended Use/Indications for Use

The ETHICON™ 4000 45mm and ETHICON™ 3D 45mm 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 instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney, and spleen.

VII. Technological Comparison

Characteristic	**Subject Device (K252739)-** The ETHICON™ 4000 45mm and ETHICON™ 3D 45mm Reloads	**Predicate Device (K250835)-** The ETHICON™ 4000 60mm and ETHICON™ 3D 60mm Reloads
Indication for Use	The ETHICON™ 4000 45mm 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 instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney, and spleen.	Same
Intended Use	Transection, resection, and/or creation of anastomoses.	Same
Contraindications	○ Do not use the instruments on	Same

Characteristic	**Subject Device-** The ETHICON™ 4000 45mm and ETHICON™ 3D 45mm Reloads	**Predicate Device-** The ETHICON™ 4000 60mm and ETHICON™ 3D 60mm Reloads
	the aorta. o Do not use the instruments on ischemic or necrotic tissue. o Do not use any endocutter on major vessels without making provision for proximal and distal control. o Tissue thickness should be carefully evaluated before firing any stapler. If tissue cannot comfortably compress to the closed staple height listed in the table or easily compresses to less than the closed staple height listed in the table, the tissue is contraindicated as it may be too thick or too thin for the selected staple size. o These instruments are not intended for use when surgical stapling is contraindicated	
Sterile, Single Patient Use	Yes	Same
Staple Rows	3D staples on the outer 2 rows 2D B-shaped staples on the inner row (closest to knife)	Same
Staple Form	3D staple form & 2D B-shaped staple form	Same
Sterilization Method	Stapler: EO Sterilization Reload: Gamma Irradiation	Same
Shelf Life	3 Years	Same
Biocompatibility of Materials	Meets ISO 10993-1	Same
Packaging Materials	Stapler: PETG Tray with Tyvek Lid Reload: Flexible Nylon Film Blister with Tyvek Lid	Same
Jaw Aperture	45mm Anvil: 19.1mm	60mm Anvil: 22mm
Two-Position Anvil Tip	The distal portion of the anvil has a mechanism to toggle between the straight and curved configurations.	The anvil only allows for a straight configuration.

Characteristic	**Subject Device-** The ETHICON™ 4000 45mm and ETHICON™ 3D 45mm Reloads	**Predicate Device-** The ETHICON™ 4000 60mm and ETHICON™ 3D 60mm Reloads
Staple Line Length	45 mm	60 mm
Cut Line Length	42 mm	57 mm

VIII. Non-Clinical and/or Clinical Tests

The nonclinical tests that have been submitted include vessel sealing, formed staple height, staple form quality, and staple line integrity in solid organs. Pre-clinical data includes hemostasis performance in solid organs and vessels. Performance test data (bench and animal) demonstrates that the subject device is substantially equivalent to the predicate device. Other preclinical testings were leveraged from previous version of the cleared device.

Clinical Tests

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

IX. Conclusion

In all cases the subject devices passed the functional requirements of the device features. The ETHICON™ 4000 45mm and ETHICON™ 3D 45mm Reloads have been demonstrated to be safe and effective to include in the ETHICON™ 4000 Stapler with ETHICON™ 3D Reloads portfolio.

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.