July 03, 2024

Ethicon Endo-Surgery, LLC
Jisha Mlynarczyk
Regulatory Affairs Specialist
475 Calle C
Guaynabo, PR 00969
Puerto Rico

Re: K241629
Trade/Device Name: ECHELON 3000 45mm Compact Stapler (ECH45C); Echelon 3000 45mm Standard Stapler (ECH45S); Echelon 3000 45mm Long Stapler (ECH45L); Echelon 3000 60mm Compact Stapler (ECH60C); Echelon 3000 60mm Standard Stapler (ECH60S); Echelon 3000 60mm Long Stapler (ECH60L)

Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical Stapler
Regulatory Class: Class II
Product Code: GAG
Dated: June 6, 2024
Received: June 6, 2024

Dear Jisha Mlynarczyk:

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.

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: 2024.07.03 12:06:48 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
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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)*

K241629

Device Name

ECHELON 3000 45mm Compact Stapler (ECH45C);
Echelon 3000 45mm Standard Stapler (ECH45S);
Echelon 3000 45mm Long Stapler (ECH45L);
Echelon 3000 60mm Compact Stapler (ECH60C);
Echelon 3000 60mm Standard Stapler (ECH60S);
Echelon 3000 60mm Long Stapler (ECH60L)

Indications for Use *(Describe)*

The ECHELON™ 3000 and ECHELON ENDOPATH™ families of staplers and 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.

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.**

# 510(k) Summary

**Contact Details:**

**Applicant Name**: Ethicon Endo-Surgery LLC
**Applicant Address**: 475 Calle C Guaynabo PR 00969 Puerto Rico
**Applicant Contact Telephone**: 2247153941
**Applicant Contact:** Mrs. Jisha Mlynarczyk
**Applicant Contact Email**: JMlynarc@its.jnj.com

**Device Name:**

**Device Trade Name:**

ECHELON™ 3000 45mm Compact Stapler (ECH45C)
ECHELON™ 3000 45mm Standard Stapler (ECH45S)
ECHELON™ 3000 45mm Long Stapler (ECH45L)
ECHELON™ 3000 60mm Compact Stapler (ECH60C)
ECHELON™ 3000 60mm Standard Stapler (ECH60S)
ECHELON™ 3000 60mm Long Stapler (ECH60L)

**Common Name:** Surgical Stapler
**Classification Name:** Stapler, Surgical
**Regulation Number:** 878.4740
**Product Codes:** GAG

**Legally Marketed Predicate Devices:**

| Predicate Number | Predicate Trade Name | Product Code |
|---|---|---|
| **K213633** | **ECHELON™ 3000 45mm Stapler** | **GAG** |
| **K213633** | **ECHELON™ 3000 60mm Stapler** | **GAG** |

**Device Description Summary**

The ECHELON™ 3000 45mm and 60mm Staplers 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. The ECHELON™ 3000 Staplers 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.

The devices are available in two different configurations (ECHELON™ 3000 45mm Staplers and ECHELON™ 3000 60mm Staplers) and three different shaft lengths (Compact, Standard, and Long). The device utilizes battery power to fire the device. The instruments are packaged with a primary lithium battery pack that must be installed prior to use. There are specific requirements for disposing of the battery pack noted in the Instructions for Use Battery Pack Disposal section of the package insert.

The instruments are packaged without a reload and must be loaded prior to use. A staple retaining cap on the reload protects the staple leg points during shipping and transportation. The instrument lock-out feature is designed to prevent a used or improperly installed reload from being re-fired or an instrument from being fired without a reload.

**Intended Use/Indications for Use**:

The ECHELON™ 3000 and ECHELON ENDOPATH™ families of staplers and 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.

**Indications for Use Comparison**:

There is no change to Indications for Use.
Indications for Use are as follows. The ECHELON™ 3000 and ECHELON ENDOPATH™ families of endoscopic linear cutters 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 buttressing materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney, and spleen.

**Technological Comparison**

Both Subject and Predicate devices are sterile, single-patient use devices that share the same technological characteristics with respect to the materials, energy source, and principals of operation of the devices. The devices-simultaneously cut and staple tissue. There are six staggered rows of staples created with both Subject and Predicate devices, three on either side of the cut line. The ECHELON™ 3000 45 mm Staplers have a staple line that is approximately 45 mm long and a cut line that is approximately 42 mm long. The ECHELON™ 3000 60 mm Staplers have a staple line that is approximately 60 mm long and a cut line that is approximately 57 mm 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. Both Subject and Predicate devices use embedded software- a microprocessor printed circuit board assembly (PCBA), for powered articulation and firing of the device. The devices utilize battery power to fire the device.

The Subject and the Predicate devices differ primarily in the dimensional and material changes to the shifter plate component of the device. The Shifter Plate component enables the transition from firing mode to articulation mode or the vice versa. The Shifter Plate component is a non-patient contacting component and the material change to the component is not new as it is used elsewhere in the predicate device.

The changes do not affect the intended use of the device, nor do they alter the fundamental scientific technology of the device.

**Non-Clinical and/or Clinical Tests Summary & Conclusions**

The following performance data were provided in support of the substantial equivalence determination.

Design Verification was conducted to evaluate the material and dimensional changes to the Shifter Plate component. The Closure Force during Device shifting testing was completed against the predicate Design Requirement using success criteria with the original validated Test Method to confirm acceptable performance of the Subject device.

In addition, side by side component level testing was completed to confirm equivalent or better strength and wear properties in comparison with the predicate design *(i.e.: Component withstand strength, Pinning for Device assembly, and cyclic wear during Device closure)*. The intent of this additional testing was for comparison purposes and the device component met the success criteria all for testing performed.

Performance Qualification was completed with the new Shifter Plate component and demonstrated the ability to consistently produce acceptable product meeting all predetermined functional, safety, and design requirements.

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

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