April 8, 2022
Ethicon Endo-Surgery, LLC
Ekta Patel
Senior Regulatory Affairs Specialist
4545 Creek Road
Blue Ash, Ohio 45242

Re: K213633
Trade/Device Name: ECHELON 3000 45mm Stapler, ECHELON 3000 60mm Stapler
Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical Stapler
Regulatory Class: Class II
Product Code: GAG
Dated: March 8, 2022
Received: March 9, 2022

Dear Ekta Patel:

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,

Mark Trumbore
Assistant Director
DHT4A: Division of General 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213633

Device Name
ECHELON™ 3000

Indications for Use *(Describe)*
The ECHELON FLEX™, ECHELON™ 3000, and ECHELON ENDOPATH™ 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

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

Contact: Ekta Patel
Senior Regulatory Affairs Specialist
Ethicon Endo-Surgery, Inc.
Phone: 513-337-1124
Email: epatelho@its.jnj.com

Date Prepared: November 15, 2021

II. SUBJECT DEVICES

Trade Names:

- ECHELON™ 3000 45mm Stapler
- ECHELON™ 3000 60mm Stapler

Common or Usual Name: Surgical Stapler
Classification Name: Surgical Stapler (21 CFR 878.4740)
Regulatory Class: II
Product Code: GAG

III. PREDICATE DEVICES

Predicate Device 510(k) Number	**Predicate Device Name**	**Predicate Device Product Codes**
K163454	ECHELON FLEX™ 45mm Powered Plus Articulating Endoscopic Linear Cutters	PSEE45A, PLEE45A, PCEE45A
K160521	ECHELON FLEX™ 60mm Powered Plus Compact Articulating Endoscopic Linear Cutters	PCEE60A
K140560	ECHELON FLEX™ 60mm Powered Plus Articulating Endoscopic Linear Cutters	PSEE60A and PLEE60A

These predicates have not been subjected to a recall related to these design modifications.

Reference device(s):

- **K-number K202665:** references 45mm and 60mm ECHELON FLEX™ Powered Plus Articulating Endoscopic Linear Cutters, cleared under a Special 510(k) Premarket Notification.

  *Both K202665 and current subject device ECHELON™ 3000 has the same predicate device

- **K-numbers K163454 and K183435:** references 45mm and 60mm ECHELON ENDOPATH™ (reloads) which are used in conjugation with ECHELON™ 3000 45 mm and 60mm Stapler respectively. There are no modifications to the reloads; this 510(k) submission is associated with the ECHELON™ 3000 stapler only.

Table 5-1: Reference devices* (Reloads) used with the Subject Devices (Stapler)

Reference Device K-Number	**Reference Device Name**	**Reference Device Product Codes**
K163454	ECHELON ENDOPATH™ Endoscopic Linear Cutter Reloads, 45mm (+ Gripping Surface Technology)	GST45B, GST45D, GST45G, GST45T, GST45W
K183435	ECHELON ENDOPATH™ Endoscopic Linear Cutter Reloads, 60mm (+ Gripping Surface Technology)	GST60B, GST60D, GST60G, GST60T, GST60W

*No change to stapler reloads

Table 5-2: Reload codes and corresponding reload color

Reloads Codes for 45mm	**Reload Codes for 60mm**	**Corresponding Reload Color**
GST45**B**	GST60**B**	Blue
GST45**D**	GST60**D**	Gold
GST45**G**	GST60**G**	Green
GST45**T**	GST60**T**	Black
GST45**W**	GST60**W**	White

*No change to stapler reloads

IV. DEVICE DESCRIPTION

The ECHELON™ 3000 45 mm and 60 mm 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 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.

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. Refer to the Battery Pack Disposal section.

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 instruments' lock-out feature is designed to prevent a used or improperly installed reload from being refired or an instrument from being fired without a reload.

V. INDICATIONS FOR USE

ECHELON FLEX™, ECHELON™ 3000, and ECHELON ENDOPATH™ 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.

Note: only the ECHELON™ 3000 staplers are the Subject of this 510(k) submission.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

ECHELON™ 3000 Stapler is substantially equivalent to ECHELON FLEX™ Powered Plus Articulating Endoscopic Linear Cutters with respect to operating principle of device and Intended use of the device. Both the devices are sterile, single use device which are powered using lithium battery. The key technological difference between the subject and the predicate device is the embedded software in Subject device to fire the device.

The subject and predicate staplers have the following identical features:

- Indication for Use
- Intended use
- Contraindications
- Compatible Reloads (Subject device will be using the previously 510k cleared reloads used with the predicate device)
- Materials
- Operational principles

The following differences exist between the subject and predicate staplers:

- Control Mechanism - Embedded software
- Sterilization Method
- Powered Articulation
- Increased Articulation and Jaw aperture
- Multifunctional “Home button”
- Haptic alerts
- Anvil Component Dimension Change
- Motor Firing Speed Change

VII. PERFORMANCE DATA:

The following performance data demonstrate that the subject device is substantially equivalent to the predicate device and the differences between the devices were found not to affect safety or performance.

Bench Testing: Formed Staple Height (FSH), Staple Line Integrity (SLI), Force to Close, Staple Line Visual Analysis, Staple Line Strength.

Animal Testing: In-vivo testing evaluations included

- Acute Hemostasis evaluation study
- Tissue Healing response, Survival Study

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

Biocompatibility: studies was performed and confirmed that the Subject device is biocompatible for the intended patient contact profile.

Electrical Safety and Electromagnetic Compatibility: The Electrical Safety and Electromagnetic Compatibility of the subject device conforms with the requirements of the FDA recognized standards for Medical Electrical Equipment.

Human Factors Testing/Usability Study: was conducted to evaluate the performance of the subject device and Instruction for Use (IFU) and establish objective evidence that the device can be used safely as intended by representative users in the intended environment.

VII. CONCLUSIONS

The conclusions of the testing criteria demonstrate that the subject device, ECHELON™ 3000 performs substantially equivalent to the predicate device and does not raise new questions of safety and effectiveness.