October 15, 2020

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

Re: K202665
Trade/Device Name: Echelon Flex 45mm Powered Plus Articulating Endoscopic Linear cutters
Echelon Flex 60mm Powered Plus Articulating Endoscopic Linear cutters
Echelon Endopath Endoscopic Linear Cutter Reloads, 45mm
Echelon Endopath Endoscopic Linear Cutter Reloads, 60mm

Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: September 10, 2020
Received: September 14, 2020

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,

For Cindy Chowdhury
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202665

Device Name
ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX families of endoscopic linear cutters and reloads

Indications for Use *(Describe)*
ECHELON, ECHELON ENDOPATH™ and ECHELON FLEX families of endoscopic linear cutters and reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, 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.

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.

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510(k) Summary

I. SUBMITTER

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

Phone: 513-337-1124
Fax: 513-337-4366

Contact Person: Ekta Patel, MS, MSM
Date Prepared: September 10, 2020

II. SUBJECT DEVICES

Trade Names:

- **ECHELON FLEX™ 45mm Powered Plus Articulating Endoscopic Linear Cutters**
- **ECHELON FLEX™ 60mm Powered Plus Articulating Endoscopic Linear Cutters**

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

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):

- **Reference K-numbers K163454 and K183435**: reference to 45mm and 60mm ECHELON ENDOPATH™ (reloads) which are used in conjugation with 45mm and 60mm ECHELON FLEX^{TM} Powered Plus Articulating Endoscopic Linear Cutters respectively. There are no modifications to the reloads; this 510(k) submission is only subjected to the ECHELON FLEX^{TM} Powered Plus Articulating Endoscopic Linear Cutters.

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 FLEX™ Powered Plus Articulating Endoscopic Linear Cutters 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 FLEX™ 45 Powered Plus instruments have a staple line that is approximately 45 mm long and a cut line that is approximately 42 mm long.

The ECHELON FLEX™ 60 Powered Plus instruments 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, ECHELON ENDOPATH™ and ECHELON FLEX families of endoscopic linear cutters and reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, 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.

There is no change to the indications for Use. Note: only the ECHELON FLEX Powered Plus Articulating endoscopic linear cutters are the subject of this 510(k) submission.

VI. COMPARISON OF CHARACTERISTICS WITH THE PREDICATE DEVICES

A) Technological Characteristic:

Surgical stapling is the technological principle for both the subject and predicate device. It is based on the use of endoscopic instrumentation for transection, resection, and/or creation of anastomoses.

The subject and predicate staplers have the following identical features:

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

The following differences exist between the subject and predicate staplers:

- Anvil Component Dimension Change
- Motor Firing Speed Change
- Channel Change (60 mm only)

B) Performance Data:

Risk analyses for each device modification are provided, according to the 2014 FDA Guidance for Industry and Food and Drug Administration Staff, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*. Verification testing to confirm device modifications do not raise new issues of safety or effectiveness have been conducted.

Clinical studies:

Clinical studies were not required to demonstrate substantial equivalence.

Bench Testing:

All verification requirements met criteria for success. The determination of substantial equivalence relied on testing including bench studies that evaluated consistent staple formation.

Formed Staple Height (FSH), Staple Line Integrity (SLI), Force to Close, Staple Line Reinforcement compatibility, Staple Line Visual Analysis, Reload installation Force, Feedback/Safety System-Reliability -Lockout, Firing System – Stall Force – Low and Firing System – Return Home position were evaluated for the subject device to support substantial equivalence to the predicate device.

Sterilization:
The subject device will be sterilized by Cobalt 60 irradiation. The device will be validated to a minimum sterilization (radiation) dose of 25kGy to achieve a 10^{-6} sterility assurance level (SAL).

The sterilization process will be validated, and sterilization dose will be established per the requirements of the following FDA recognized standards:

ISO 11737-1:2018: Sterilization of health care products – Microbiological methods Part 1: Determination of a population of microorganisms on products. (FDA Recognized Number –14-514)

ISO 11737-2:2009: Sterilization of medical devices – Microbiological Methods – Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process. (FDA Recognized Number 1-327)

ISO 11137-1:2006/AMD 2:2018: Sterilization of health care products – Radiation – Part 1: Requirements for development validation and routine control of a sterilization process for medical devices (FDA Recognized Number 14-528)

ISO 11137-2:2013: Sterilization of medical devices – Radiation – Part 2: Establishing the sterilization does (FDA Recognized Number 14-409)

Biocompatibility Testing:
Biocompatibility testing was not required for this submission as no new materials were introduced on this device. All materials are already cleared under the predicate device submission.

Electrical Safety and Electromagnetic Compatibility:
The Electrical Safety and Electromagnetic Compatibility of the subject device conforms with the requirements of the following FDA recognized standards:

IEC 60601-1-6:2013: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability (FDA Recognition Number 5-89)

IEC 60601-1-2:2014: Medical electrical equipment – Pat 1-6: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbance (FDA Recognition Number 19-8)

VII. CONCLUSIONS

The risk profile of the device has not changed as a result of the described changes while having the same intended use as the predicate device; furthermore, the performance of the modified device is consistent with the predicate device and does not raise any new questions of safety and effectiveness.