May 07, 2024

Lexington Medical, Inc.
Sali Gully
Sr. Regulatory Affairs Specialist
23 Crosby Drive
Bedford, Massachusetts 01730

Re: K234039
Trade/Device Name: AEON Endoscopic Powered Stapler
Regulation Number: 21 CFR 878.4740
Regulation Name: Surgical Stapler
Regulatory Class: Class II
Product Code: GAG, GDW
Dated: December 20, 2023
Received: December 21, 2023

Dear Sali Gully:

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: 2024.05.07 08:57:51 -04'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
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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.

510(k) Number *(if known)*
K234039

Device Name
AEON™ Endoscopic Powered Stapler

Indications for Use *(Describe)*
The AEON Endoscopic Powered Stapler has applications in general, abdominal, gynecologic, and pediatric surgery for resection, transection, and creation of anastomoses. The instrument may be used for transection and resection of liver substance, hepatic vasculature, 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.

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510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR Part 807.92, the following summary of information is provided:

A. Submitter Information:

Sali Gully
Sr. Regulatory Affairs Specialist
Lexington Medical, Inc.
23 Crosby Drive
Bedford, Massachusetts 01730, USA
Telephone: (617) 209-9817

Date Prepared: May 7, 2024

B. Device Information

Trade or Proprietary Name:	AEON™ Endoscopic Powered Stapler
Common Name:	Surgical Stapler
Classification Name:	Implantable Staple Surgical Stapler
Regulation Number:	21 CFR 878.4740, 21 CFR 878.4750
Regulation Class:	II
Primary Product Code:	GAG
Secondary Product Code:	GDW

C. Predicate Devices

510(k) number: K222210
Product Name: AEON Endoscopic Stapler
Manufacturer: Lexington Medical Inc.
Classification Name: Surgical Stapler, Implantable Staple
Regulation Number: 21 CFR 878.4740, 21 CFR 878.4750
Product Code: GAG, GDW
Regulation Class: II

Reference Device

510(k) number: K163454
Product Name: ECHELON FLEX 45mm Powered Plus Articulating Endoscopic Linear Cutters, ECHELON ENDOPATH Endoscopic Linear Cutter Reloads, 45mm
Manufacturer: ETHICON ENDO-SURGERY, LLC
Classification Name: Implantable Staple
Regulation Number: 21 CFR 878.4750
Product Code: GDW
Regulation Class**:** II

D. Device Description

The AEON Endoscopic Powered Stapler system is an endoscopic linear cutter and reload system that simultaneously cut and staple tissue. The AEON Endoscopic Powered Stapler places two, triple-staggered rows of titanium staples while simultaneously transecting between the two triple-staggered rows of staples.

The AEON Endoscopic Powered Stapler system is composed of an AEON Endoscopic Powered Stapler Handle and the AEON Endoscopic Stapler Reloads. Multiple staple handle lengths and multiple staple sizes are available to accommodate various tissue thicknesses.

The AEON Endoscopic Powered Stapler uses software to control operation of the stapler and is AC powered. The device is sterile packaged (Ethylene Oxide) and single use. The AEON Endoscopic Powered Stapler Handle may be reloaded and fired up to 20 times in a single procedure.

E. Indications for Use

The AEON Endoscopic Powered Stapler has applications in general, abdominal, gynecologic, and pediatric surgery for resection, transection, and creation of anastomoses. The instrument may be used for transection and resection of liver substance, hepatic vasculature, biliary structures, pancreas, kidney and spleen.

F. Technological Characteristics

Surgical stapling is the technological principle for both the subject and the predicate devices. Instrumentation is used for transection, resection, and/or creation of anastomoses. Overall, the subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate device through comparison in areas including design, indications, material composition, principle of operation, function, and packaging. Additionally, the reference device is used to support the performance testing for powered stapler applications.

	AEON Endoscopic Powered Stapler	**AEON Endoscopic Stapler**	**The ECHELON ENDOPATH / ECHELON FLEX**	
ITEM	**Subject Device (K234039)**	**Predicate Device (K222210)**	**Reference Device (K163454)**	**SE**
510(k) Number	K234039	K222210	K163454	Yes
Product Code	GDW, GAG	GDW, GAG	GDW	Yes
Regulation No.	878.4750, 878.4740	878.4750, 878.4740	878.4750	Yes
Class	II	II	II	Yes

	AEON Endoscopic Powered Stapler	**AEON Endoscopic Stapler**	**The ECHELON ENDOPATH / ECHELON FLEX**	
ITEM	**Subject Device (K234039)**	**Predicate Device (K222210)**	**Reference Device (K163454)**	**SE**
Indications for Use	The AEON Endoscopic Powered Stapler has applications in general, abdominal, gynecologic, and pediatric surgery for resection, transection, and creation of anastomoses. The instrument may be used for transection and resection of liver substance, hepatic vasculature, biliary structures, pancreas, kidney and spleen.	The AEON Endoscopic Stapler has applications in general, abdominal, gynecologic, pediatric, and thoracic surgery for resection, transection, and creation of anastomoses. The instrument may also be used for transection and resection of liver substance, hepatic vasculature, biliary structures, pancreas, kidney, and spleen.	The ENDOPATH ECHELON 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 for 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.	Yes
Reload Features	Tissue Stop	Tissue Stop	Tissue Stop	Yes
	Anvil	Anvil	Anvil	Yes
	Cut Line	Cut Line	Cut Line	Yes
	Knife	Knife	Knife	Yes
	Cartridge	Cartridge	Cartridge	Yes
Operation Principle	Powered	Manual	Powered	Yes
Cutting Mechanism	Linear Knife	Linear Knife	Linear Knife	Yes
Cutting Length	26, 41, 56mm	26, 41, 56mm	42, 53mm	Yes
Open Staple Height	2.0, 2.5, 3.25, 4.0, 5.0mm	2.0, 2.5, 3.25, 4.0, 5.0mm	2.0, 2.6, 3.6, 3.8, 4.1, 4.2 mm	Yes
Closed Staple Height	0.75, 1.0, 1.5, 1.8, 2.2mm	0.75, 1.0, 1.5, 1.8, 2.2mm	0.75, 1.0, 1.5, 1.8, 2.0, 2.3mm	Yes
Single Patient Use	Yes	Yes	Yes	Yes
Sterilization Method	EO Sterilized	EO Sterilized	Gamma Sterilized	Yes

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject AEON Endoscopic Powered Stapler is substantially equivalent to predicate devices. The following testing or engineering rationale were provided in support of the substantial equivalence determination:

- Staple height and formation
- Staple line strength
- Staple line integrity
- Ex-vivo leak-burst pressure testing
- Articulation deflection
- Obstruction and lockout testing
- Functional lifecycle testing
- Deployment pressure
- Design validation

Software verification and validation testing was conducted, and software related documentation (enhanced documentation level) was provided per the FDA Guidance Document *Content of Premarket Submissions for Device Software Functions*.
Animal testing was performed to assess In vivo confirmation of staple line hemostasis in accordance with the FDA Guidance Document *Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery.*

Human Factors testing was executed in accordance with the FDA Guidance Document *Applying Human Factors and Usability Engineering to Medical Devices*.

Electrical safety and EMC testing were conducted on the subject device and the subject device complies with the IEC 60601-1 standard for safety and effectiveness and the IEC 60601-1-2 standard for EMC.

Additionally, biocompatibility of materials was assessed, and sterilization, packaging, distribution and shelf-life validations were executed.

The results of testing and evaluation listed above demonstrate that the subject AEON Endoscopic Powered Stapler is substantially equivalent to the predicate device.

H. Conclusions

The comparison of intended use and technological characteristics along with the non-clinical data support the safety and performance of the device. The hardware and software verification and validation demonstrate that the AEON Endoscopic Powered Stapler performs as intended in the specified use conditions.