July 11, 2025

Lexington Medical, Inc.
Sharon Timberlake
Head of Global Regulatory Affairs & Quality
23 Crosby Drive
Bedford, Massachusetts 01730

Re: K251482
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: May 9, 2025
Received: May 14, 2025

Dear Sharon Timberlake:

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

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)*
K251482

Device Name

AEON™ Endoscopic Powered Stapler

Indications for Use *(Describe)*

The AEON™ Endoscopic Powered Stapler has applications in general, abdominal, gynecologic, pediatric, and thoracic 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.

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510(k) Summary

K251482

This 510(k) Summary is prepared in accordance with the requirements of 21 CFR 807.92

1. **Date Prepared**

   July 11, 2025

2. **Submitter & 510(k) Owner Information**

Submitter:	Lexington Medical, Inc. 23 Crosby Drive Bedford, Massachusetts 01730
Official Correspondent:	Sharon L. Timberlake, MSHS, RAC, CCRA Head of Global Regulatory Affairs & Quality Telephone: (617) 957-1434 Email: sharon.timberlake@lexington-med.com

3. **Device Information**

Trade 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

4. **Predicate & Reference Device Identification**

Predicate Device Trade Name:	AEON™ Endoscopic Stapler
510(k) Number:	K222210
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

Reference Device Trade Name:	AEON™ Endoscopic Powered Stapler
510(k) Number:	K234039
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

5. Device Description

The AEON Endoscopic Powered Stapler system is composed of the AEON Endoscopic Powered Stapler Handle ("Powered Handle") and AEON Endoscopic Stapler Reloads ("Reloads"). 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 Powered Handle may be reloaded and fired up to 20 times in a single procedure. The Powered Handle is available in three different lengths (60mm, 160mm and 260mm) and the Reloads are available in multiple staple sizes to accommodate various tissue thicknesses.

The AEON Endoscopic Powered Stapler uses software to control the operation of the stapler and is AC powered. The device is sterile packaged and is labeled for single use.

6. Indications for Use

The AEON™ Endoscopic Powered Stapler has applications in general, abdominal, gynecologic, pediatric, and thoracic 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.

7. Technological Characteristics Compared to the Predicate

Surgical stapling is the technological principle for both the subject and the predicate device. Just like its predicate and reference devices, the AEON Endoscopic Powered Stapler is used in surgical procedures to staple and cut tissue for resection, transection, and creation of anastomoses. The same Reloads are attached to the subject device, predicate device and reference device for use in all surgical applications. There are no changes to the Powered Handle product specifications when compared to its predicate as a result of the expanded Indications for Use. The subject device and predicate device both share the expanded indications to include thoracic applications.

Item	**AEON Endoscopic Powered Stapler** (Subject Device)	**AEON Endoscopic Stapler** (Predicate Device)	**AEON Endoscopic Powered Stapler** (Reference Device)	**SE**
510(k) Number	Not Assigned	K222210	K234039	Yes
Product Code	GAG, GDW	GAG, GDW	GAG, GDW	Yes
Regulation Number	878.4750, 878.4740	878.4750, 878.4740	878.4750, 878.4740	Yes
Classification	II	II	II	Yes

Item	**AEON Endoscopic Powered Stapler** (Subject Device)	**AEON Endoscopic Stapler** (Predicate Device)	**AEON Endoscopic Powered Stapler** (Reference Device)	**SE**
Indications for Use/ Intended Use	The AEON™ Endoscopic Powered Stapler has applications in general, abdominal, gynecologic, pediatric, and thoracic 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 be used for transection and resection of liver substance, hepatic vasculature, biliary structures, pancreas, kidney and spleen.	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.	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
Contains Software	Yes	No	Yes	Yes
Cutting Mechanism	Linear Knife	Linear Knife	Linear Knife	Yes
Cutting Length (mm)	26, 41, 56	26, 41, 56	26, 41, 56	Yes
Open Staple Height (mm)	2.0, 2.5, 3.25, 4.0, 5.0	2.0, 2.5, 3.25, 4.0, 5.0	2.0, 2.5, 3.25, 4.0, 5.0	Yes
Closed Staple Height (mm)	0.75, 1.0, 1.5, 1.8, 2.2	0.75, 1.0, 1.5, 1.8, 2.2	0.75, 1.0, 1.5, 1.8, 2.2	Yes
Single-Use	Yes	Yes	Yes	Yes
Sterilization Method	EO Sterilized	EO Sterilized	EO Sterilized	Yes

8. Performance Data

Bench and Animal

Non-clinical testing (bench and animal) was not required to support the expanded Indications for Use. The subject device is identical to the reference device (K234039) in design, technological characteristics, materials, software, IEC/EMC electrical requirements, packaging and performance characteristics. Therefore, additional biocompatibility testing, sterilization validation, software validation, electrical safety and IEC/EMC testing are not required since this information has been previously reviewed in K234039. Also, MR safety information is unchanged.

The subject device and its reference device share the exact same principles of operation along with Instructions for Use and product labeling. As a result, human factors testing is not applicable to support the expanded Indications for Use.

Real-world Clinical Evidence

Real-world evidence data was provided to support the expanded Indications for Use of the subject device. The real-world evidence addressed the safety and effectiveness of the AEON™ Endoscopic Powered Stapler specific to thoracic applications. The results of the data conclude that the device is safe and effective for use for thoracic applications.

9. Conclusions

The subject device and predicate device have the same intended use and principles of operation. The subject device, predicate device and reference device utilize the same Reloads to perform their intended use. The expanded Indications for Use, namely to include thoracic applications, is supported by real-world evidence data to demonstrate substantially equivalent safety and effectiveness of the subject device when used in thoracic applications.