April 21, 2023

Lexington Medical Inc.
Rainer Maas
Director of QA/RA
23 Crosby Drive
Bedford, Massachusetts 01730

Re: K222210
Trade/Device Name: AEON Endoscopic Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: March 17, 2023
Received: March 17, 2023

Dear Rainer Maas:

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 -S
Digitally signed by Mark Trumbore -S
Date: 2023.04.21 08:07:48 -04'00'

Mark Trumbore, Ph.D.
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)*
K222210

Device Name
AEON™ Endoscopic Stapler

Indications for Use *(Describe)*
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.

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

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Submitter Information

Lexington Medical, Inc.
23 Crosby Drive
Bedford, Massachusetts 01730 USA

2. Contact Person

Rainer Maas
Position: Director of QA/RA
Tel: +1 978-273-1946
Email: rainer@lexington-med.com

3. Date Prepared

03/16/2023

4. Proposed Device Identification

Device Name: AEON™ Endoscopic Stapler
Device Common Name: Stapler
Classification Name: Staple, Implantable
Classification Regulation: 21 CFR 878.4750, 21 CFR 878.4740
Device Class: II
Classification Panel: General & Plastic Surgery
Primary Product Code: GAG
Secondary Product Code: GDW

5. Predicate Device Identification

510(k) Number: K201882
Product Name: AEON™ Endoscopic Stapler
Manufacturer: Lexington Medical Inc.

Predicate Device:

510(k) Number: K201882
Product Name: AEON™ Endoscopic Stapler
Manufacturer: Lexington Medical, Inc.

Reference Device:

510(k) Number: K163454
Product Name: The ENDOPATH ECHELON and ECHELON FLEX families of endoscopic linear cutters and reloads
Manufacturer: Ethicon Endo-surgery, LLC

6. Device Description

The AEON™ Endoscopic Stapler places two triple-staggered rows of titanium staples while simultaneously transecting between the two triple-staggered rows of staples. The size of the staples and staple line length are based on the selection of the Stapler Reload.

This 510(k) revises the labeling, including indications, contraindications, and warnings, for the AEON Endoscopic Stapler.

7. Indications For Use

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

8. Technological Characteristics

The AEON™ Endoscopic Stapler is identical to the predicate device with the exception of modified labeling.

	Proposed Device	**Predicate Device**
ITEM	**AEON Endoscopic Stapler**	**AEON Endoscopic Stapler K201882 (currently marketed device)**
Product Code	GAG, GDW	GDW
Regulation No.	21 CFR 878.4750 21 CFR 878.4740	21 CFR 878.4750
Class	II	II
Indications for Use	The AEON™ Endoscopic Stapler has applications in general, abdominal, gynecologic, pediatric, and thoracic 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.
Configuration	Same	Tissue Stop
		Anvil
		Cut Line
		Blade
		Cartridge
Operation Principle	Same	Manual

Cutting Mechanism	Same	Linear Knife
Suture Length	Same	30, 45, 60mm
Open Staple Height	Same	2.0, 2.5, 3.25, 4.0, 5.0mm
Staple Material	Same	Titanium
Stapler Materials	Stainless Steel, Polycarbonate	Stainless Steel, Polycarbonate
Single Patient Use & Disposable	Same	Yes
Labeling	Conforms to 21 CFR Part 801	Conforms to 21 CFR Part 801

9. Performance Data

A combination of real-world evidence and published clinical studies was provided to support the revised labeling.

The real-world evidence addressed the safety and effectiveness of the AEON™ Endoscopic Stapler in the liver, spleen, and pancreas. The results of the retrospective clinical studies show no complications associated with the AEON™ Endoscopic Stapler thus concluding the device safe and effective for use in expanded indications.

10. Conclusion

The proposed device, the AEON™ Endoscopic Stapler, is demonstrated to be as safe and as effective as the predicate device based on performance testing, intended use, and technological characteristics.