October 9, 2020

Lexington Medical Inc.
Rainer Maas
Director of QA/RA
11 Executive Park Drive
Billerica, Massachusetts 01862

Re: K201882
Trade/Device Name: AEON Endoscopic Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: July 7, 2020
Received: July 8, 2020

Dear Mr. 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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting 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)*
K201882

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

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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Section 3 – 510(k) Summary

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

1. Submitter Information

Lexington Medical, Inc.
11 Executive Park Drive
Billerica, Massachusetts 01862 USA

2. Contact Person

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

3. Date Prepared

July 6, 2020

4. Proposed Device Identification

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

5. Predicate Device Identification

510(k) Number: K182380
Product Name: AEON™ Endoscopic Stapler
Manufacturer: Lexington Medical, Inc.

6. Device Description

The AEON™ Endoscopic Stapler places two, triple-staggered rows of titanium staples and simultaneously divides the tissue from a central line. The size of the staples and staple line length are based on the selection of the Stapler Reload open staple height and staple line length. The AEON™ Endoscopic Stapler handle and reload are sterile, single use devices.

The modification presented in this 510(k) is to remove the “MR Unsafe” from the MRI Safety Information section of the Instructions for Use (IFU).

7. Indications for Use Statement

The AEON™ Endoscopic Stapler has applications in general, abdominal, gynecologic, pediatric, and thoracic surgery for resection, transection, and creation of anastomoses.

8. Substantial Equivalence

The indications for use and intended use of the modified device are ***identical*** to the predicate device.

The proposed modification and predicate device (K182380) have the same operating principle and mechanism of action. The user interface and operation instructions have minor changes that do not affect the safety or efficacy of the modified device. The materials comprising the modified device are ***identical*** to the predicate device. Both devices fire staples made of ***identical*** Unalloyed Titanium per ASTM F67. Staple raw material, forming process, cleaning/passivation, and assembly processes are ***identical***. Both devices are sealed in packaging with minor changes that do not affect the safety or efficacy of the modified device. Both devices are sterilized with the ***identical*** Ethylene Oxide (ETO) gas sterilization cycle to a Sterility Assurance Level of 10^{-6}.

The proposed modification and predicate device (K182380) have the same technological characteristics, except for the change to the IFU to remove “MR Unsafe” for the MRI Safety Information section. The proposed modification does not raise any additional questions of safety and effectiveness. Testing of the proposed modification shows that all stapler reload sizes meet the ASTM standards for removal of the “MR Unsafe” designation and that the proposed modification is substantially equivalent to the predicate device.

9. Performance Data

The following nonclinical tests were conducted with the AEON™ Endoscopic Stapler to verify that the proposed device is as safe and as effective as the predicate device, performs as intended, and meets all design specifications:

Testing consisted of the following performance tests for the worst-case staple line size:

i) ASTM F2182 “RF Heating”
ii) ASTM F2052 “Force”
iii) ASTM F2213 “Torque”
iv) ASTM F2119 “Image Artifact”
v) ASTM F2503 “Marking Medical Devices”

This submission does not include data from Clinical Studies.

10. Materials

All materials (including the implantable Titanium staple material), material handling and cleaning processes, and sterilization methods of the proposed modified AEON™ Endoscopic Stapler are ***identical*** to the predicate device AEON™ Endoscopic Stapler (K182380).

11. Conclusion

The proposed device, a modified version of the AEON™ Endoscopic Stapler, is demonstrated to be as safe and as effective as the predicate device based on performance testing, and is determined to be substantially equivalent to the predicate device based on performance testing, intended use, and technological characteristics.