



Food and Drug Administration
10903 New Hampshire Avenue
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February 1, 2018

Lexington Medical, Inc.
Ms. Donna Gasper
Management Representative
11 Executive Park Drive
Billerica, MA 01862

Re: K173443

Trade/Device Name: AEON™ Endoscopic Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 25, 2017
Received: November 6, 2017

Dear Ms. Gasper:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173443

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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AEON™ Endoscopic Stapler

Section 3 – 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.
11 Executive Park Drive
Billerica, Massachusetts 01862 USA

2. Contact Person

Donna L. Gasper
Position: Management Representative
Tel: +1 617-209-9817
Email: Donna@Lexington-Med.com

3. Date Prepared

11/28/2017

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: K141367
Product Name: ELC Series Endoscopic Linear Cutter and Single Use Loading Unit
Manufacturer: Touchstone International Medical Science Co., Ltd.

6. Reference Device Identification**Reference Device:**

510(k) Number: K061095

Product Name: Auto Suture™ ENDO GIA™ Stapler

Manufacturer: United States Surgical, a division of Tyco Health Group LP

Reference Device:

510(k) Number: K171589

Product Name: AEON™ Endoscopic Stapler

Manufacturer: Lexington Medical, Inc.

AEON™ Endoscopic Stapler

7. 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 is determined by the selection of the appropriate reload.

This 510(k) reports reloads with two staple sizes (gray – 2.25mm and black – 5.0mm) and in two lengths (45mm and 60mm).

8. Intended Use Statement

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

9. Technological Characteristics

The AEON™ Endoscopic Stapler is substantially equivalent to the predicate device with regards to staple technologies.

10. 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:

In Vitro:

- Rotation and Articulation
- Safety Mechanism Performance
- Firing Force
- Retraction Force
- Staple Formation
- Staple and Cut Line Length
- Staple Line Pressure Test
- Staple Line Tensile Test
- Package Integrity
- Shelf Life

In Vivo:

- Burst Evaluation
- Hemostasis Evaluation
- Staple Formation
- Biocompatibility (Cytotoxicity, Sensitization, and Irritation/Intracutaneous Reactivity per ISO-10993-1:2009 Biological evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process)
- Endotoxin Limit

This submission does not include data from Clinical Studies.

AEON™ Endoscopic Stapler

11. Materials

All materials (including the implantable Titanium staple material), material handling and cleaning processes, and sterilization methods of the AEON™ Endoscopic Stapler are identical to the reference device AEON™ Endoscopic Stapler (K171589).

All materials of the AEON™ Endoscopic Stapler are similar to the predicate device ELC Series Endoscopic Linear Cutter and Single Use Loading Unit (K141367). Chemical analysis testing was performed to confirm that the implantable Titanium staples conform with ASTM F67 – 13 Standard Specification for Unalloyed Titanium, for Surgical Implant Applications.

12. 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, and is determined to be substantially equivalent to the predicate device based on intended use and technological characteristics.