November 17, 2017

Lexington Medical Inc.
Donna Gasper
Management Representative
11 Executive Park Dr.
Billerica, Massachusetts 01862

Re: K171589
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 13, 2017
Received: October 17, 2017

Dear Donna 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.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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)*
K171589

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 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

11/16/2017

## 4. Device Identification

**510(k) Number:** K171589
**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

## 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 that is available in two staple sizes (tan – 3.25mm, purple – 4.0mm) and in one length (60mm).

**8. 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.

**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 safe and effective, 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.

## 11. Materials

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 to **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 effective as the predicate device based on performance testing, and is determined to be substantially equivalent to the predicate device based on intended use, technological characteristics, and performance testing.