October 11, 2019

Lexington Medical, Inc.
Douglas MacBride
Director of Systems Engineering
11 Executive Park Drive
Billerica, Massachusetts 01862

Re: K192235
Trade/Device Name: AEON Laparoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 15, 2019
Received: August 19, 2019

Dear Douglas MacBride:

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,

Long Chen, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192235

Device Name
AEON™ Laparoscopic Instruments

Indications for Use *(Describe)*
AEON™ Laparoscopic Instruments is a family of instruments which includes forceps, scissors, and probes which are intended to be used in general laparoscopic surgical procedures requiring the use of monopolar electrosurgical cutting and/or coagulation.

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) 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
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2. Contact Person

Douglas MacBride
Director of Systems Engineering
Tel: +1 617-209-9817
Email: Doug@Lexington-Med.com

3. Date Prepared

8/14/2019

4. Device Identification

Device Name: AEON™ Laparoscopic Instruments
Device Common Name: Electrosurgical cutting and coagulation devices
Classification Name: Electrosurgical, Cutting & Coagulation & Accessories
Classification Regulation: 21 CFR 878.4440
Device Class: II
Classification Panel: General & Plastic Surgery
Product Code: GEI

5. Predicate Device Identification

510(k) Number: K103508
Product Name: Unimax Laparoscopic Instrument
Manufacturer: Unimax Medical Systems Inc.

6. Device Description

The AEON Laparoscopic Instruments are sterile, disposable, single-use, individually-packaged surgical instruments that are designed to cut, grasp, dissect, and coagulate selected tissue in laparoscopic surgery. The instruments are designed to be used with an electrosurgical generator (to be purchased separately).

There are 10 different instrument tip configuration variants. The only difference between the 10 variants is the geometry of the tip scissors/graspers in three shaft working lengths 22cm, 33cm, and 45cm.

Scissors and forceps have a handle with rotating wheel attached to an insulated shaft with different tips, which allows the shaft and tip to rotate. They include a male cautery connector when attached to standard monopolar cautery cables and generators. Probes/Electrodes have an insulated shaft with a thermally conductive metal tip electrode. The proximal end of the shaft is attached to a handle made of an injection molded, medical grade plastic.

The proposed device is provided Ethylene Oxide (ETO) sterilized to achieve the Sterility Assurance Level (SAL) of 10^-6 and placed in a sterility maintenance package to ensure a shelf life of 3 years.

7. Indications for Use Statement

AEON™ Laparoscopic Instruments is a family of instruments which includes forceps, scissors, and probes which are intended to be used in general laparoscopic surgical procedures requiring the use of Monopolar electrosurgical cutting and/or coagulation.

8. Substantial Equivalence

The AEON™ Laparoscopic Instruments are intended to be used in general laparoscopic surgical procedures requiring the use of electrosurgical cutting and/or coagulation. The secondary function is to provide monopolar electrocautery capability to dissect and coagulate tissue. Unimax Laparoscopic Instrument (K103508) is a substantially equivalent device that has been cleared by the Food and Drug Administration. The predicate device is substantially equivalent in intended use, design, and technology characteristics and components to the AEON Laparoscopic Instruments manufactured by Lexington Medical Inc.

The proposed and predicate devices have the same intended use and mechanism of action. Both devices have the same technological characteristics and comprise substantially equivalent scissor/grasper/dissector probe tip configurations.

The AEON Laparoscopic Instruments have tip configurations that are equivalent to the predicate device product line variants. Instrument and tip dimensions are within the range established by the predicate device or similar to the predicate device range. The general shape and functional intent/mechanism of each AEON Laparoscopic Instrument is equivalent to the comparable predicate device variant.

Based on the similar intended use and technological characteristics, the AEON Laparoscopic Instruments are determined to be Substantially Equivalent (SE) to the predicate device.

9. Performance Data

Nonclinical tests were conducted with the AEON Laparoscopic Instruments to verify that the proposed device is safe and effective, performs as intended, and meets all design specifications.

Specifically, electrical safety and electromagnetic compatibility (EMC) testing was performed to:

- IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-2 Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-2:2014: Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests

Testing showed that the device complies with electrical safety and EMC standards as did the predicate device.

Biocompatibility testing was performed to:

- ISO-10993-1:2009 Biological evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical device-Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device-Part 10: Tests for irritation and skin sensitization
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.

Testing showed that the devices are non-irritating, not cytotoxic, and did not cause sensitization, supporting a finding of substantial equivalence.

Validation of sterilization and shelf life was performed to:

- ISO11607-1:2006 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM F1980-16 Standard guide for accelerated aging of sterile barrier systems for medical devices
- ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration

- ISO-11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

Testing showed that the product is sterile and supports a shelf life of 3 years.

10. Conclusion

The proposed device, the AEON™ Laparoscopic Instruments is demonstrated to be safe and effective based on performance testing, and is determined to be substantially equivalent to the predicate device based on intended use and technological characteristics.