November 22, 2019

Applied Medical Resources Corporation
Aditi Iyengar
Regulatory Affairs Specialist II
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K190331
Trade/Device Name: Applied Medical Laparoscopic Linear Cutter
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: October 23, 2019
Received: October 24, 2019

Dear Ms. Iyengar:

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)*

K190331

Device Name
Applied Medical Laparoscopic Linear Cutter

Indications for Use *(Describe)*

Applied Medical Laparoscopic Linear Cutter has applications in open and/or minimally invasive general, urologic, gynecologic, pediatric and thoracic surgery for resection, transection and/or creation of anastomosis. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen. It can be used with staple line or tissue buttressing materials.

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.

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510(k) Summary

510(K) Submitter	Applied Medical Resources Corp. 22872 Avenida Empresa Rancho Santa Margarita, CA, 92688 (949) 713-8000
Contact Person	Aditi Iyengar Regulatory Affairs Specialist II Applied Medical Resources Corp. aiyengar@appliedmedical.com Tel: (949) 713-8007 Fax: (949) 713-8205
Date of Preparation	February 12, 2019
Trade Name	Applied Medical Laparoscopic Linear Cutter
Common Name	Surgical Stapler/Implantable Staple
Classification	Regulation: 21 CFR 878.4750 Regulation Name: Implantable Staple Device Class: Class II Product Code: GDW Regulation: 21 CFR 878.4800 Regulation Name: Surgical Stapler Device Class: Class I Product Code: GAG
Predicate Device	Ethicon Echelon Flex Endopath 510(k)#: K081146 Product Code: GDW, GAG
Intended Use	The Applied Medical Laparoscopic Linear Cutter has applications in open and/ or minimally invasive general, urologic, gynecologic, pediatric and thoracic surgery for resection, transection and/or creation of anastomosis. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen. It can be used with staple line or tissue buttressing materials.

Device Description

The Applied Medical Laparoscopic Linear Cutter (LLC) is a sterile, single-use stapling system that is intended to be used for mechanically transecting, resecting, and sealing tissue during laparoscopic and open surgical procedures. The stapler places six staggered rows of titanium staples, three on either side of the transection line. The shaft can rotate freely in both directions and the jaws articulate to facilitate access to the operative site.

The Applied LLC is available in 3 different shaft lengths (20cm, 37cm, 50cm) that can each accommodate 3 different industry-standard reload lengths (60mm, 45mm, 30mm). Each of the reload lengths is available in three industry-standard reload colors and formed staple heights to accommodate various tissue thicknesses: 1.0mm (white reload), 1.5mm (blue reload), and 2.0mm (green reload).

Summary of Technological Characteristics with the Predicate Device

The subject Applied Medical Laparoscopic Linear Cutter (LLC) and the predicate Ethicon Echelon Flex Endopath are similar in technological characteristics, materials, performance, and method of operation. Both devices are intended to mechanically seal and transect tissue by placing two, triple-staggered rows of titanium staples and simultaneously dividing the stapled tissue.

The following technological differences exist between the subject and predicate staplers:

- The subject device has 3 modular components: 1) handle 2) shaft 3) reload. The predicate device has 2 components: 1) handle and shaft 2) reload.
- The subject device requires 5 trigger strokes to complete a firing while the predicate device requires 3 trigger strokes to complete a firing.
- The compact and long versions of the subject shaft differ in length from the predicate. However, this difference in shaft length does not impact staple formation.

Discussion of Performance Testing Submitted

Evidence of safety and effectiveness of the subject device in support of substantial equivalence was obtained from bench testing, preclinical testing, and biocompatibility testing. No human clinical studies were required to demonstrate the safety and effectiveness of the subject device in support of this premarket notification. A summary of the performance tests used to evaluate the technological and performance characteristics in support of substantial equivalence is presented in ***Table 5-1*** and ***Table 5-2***. All performance testing acceptance criteria were met.

Table 5-1 Bench Tests

Test	Test Objective
Firing Force	To evaluate the input force required to actuate the trigger
Leak Test	To evaluate staple line leak pressures
Articulation Testing	To evaluate device performance when fully articulated
Reinforcement Material Compatibility	To evaluate device performance with reinforcement material
Shelf Life Testing	To evaluate device performance after simulated transit and storage conditions
Staple Formation	To evaluate staple formation in media and out of media
Formed Staple Height	To measure the formed staple height
Radiograph Imaging	To evaluate location and quality of staple formation in media
Tissue Compression Evaluation	To evaluate tissue effects associated with application of the device
Crossed Staple Line	To evaluate device performance when fired across existing staple line

Table 5-2 Preclinical Tests

Test	Test Objective
21-Day Porcine Chronic Survival Study	To evaluate *in vivo* device performance including *in vivo* hemostasis and histopathological evaluations
Acute Porcine In-Vivo Study	To evaluate device performance on high pressure arteries and thin-walled veins

Biocompatibility Tests

The following biological evaluations were performed in support of substantial equivalence:

- Ethylene Oxide Residual (per ISO 10993-7)
- Material Mediated Pyrogenicity (per USP 40-NF 35:<151>)
- Cytotoxicity (per ISO 10993-5)
- Sensitization (per ISO 10993-10)
- Acute Systemic Toxicity (per ISO 10993-11)
- Intracutaneous Reactivity (per ISO 10993-10)
- Intramuscular Implant Testing (2 week and 13 week, per ISO 10993-6)

A chemical characterization and subsequent toxicological risk assessment (per ISO 10993-18) was performed to evaluate the safety of the implantable staples. Results from the testing were used to assess the following endpoints:

- Reproductive and Developmental Toxicity

- Subacute Toxicity
- Subchronic Toxicity
- Chronic Toxicity
- Genotoxicity
- Carcinogenicity

Conclusion

Based on the intended use, technological characteristics, and performance testing results, the subject Applied Laparoscopic Linear Cutter is substantially equivalent to the predicate Ethicon Echelon Flex Endopath and does not raise any new issues of safety and efficacy.