June 24, 2021

Ezisurg Medical Co., Ltd.
% Diana Hong
General Manager
Mid-Linking Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K210909
Trade/Device Name: easyEndo Lite Linear Cutting Stapler and Loading Unit for Single Use
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: March 18, 2021
Received: March 29, 2021

Dear Ms. Hong:

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.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210909

Device Name
easyEndoTM Universal Linear Cutting Stapler and Loading Units for Single Use

Indications for Use *(Describe)*
The easyEndoTM Lite Linear Cutting Stapler and Loading Units for Single Use are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general abdominal, gynecologic, thoracic, and pediatric surgical procedures.

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.

Tab #6 510(k) Summary

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

The assigned 510(k) Number: K210909

1. Date of Preparation: 06/22/2021

2. Sponsor Identification

Ezisurg Medical Co., Ltd.
Rm. 103, Bldg. 2, No.1690 Cailun Rd., China (Shanghai) Pilot Free Trade Zone, 201203 Shanghai, China

Establishment Registration Number: Not registered yet

Contact Person: Jingtian Ren
Position: Senior RA Engineer
Tel: +86-21-50456176-8026
Fax: +86-21-50676156
Email: renjingtian@ezisurg.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: easyEndo™ Lite Linear Cutting Stapler and Loading Unit for Single Use
Common Name: Stapler and Reload

Regulatory Information

Classification Name: Staple, Implantable
Classification: II
Product Code: GDW
Regulation Number: 21 CFR 878.4750
Review Panel: General&Plastic Surgery

Classification Name: Stapler, Surgical;
Classification: I
Subsequent Product Code: GAG;
Regulation Number: 21CFR 878.4800
Review Panel: General & Plastic Surgery

Indication for Use Statement:

The easyEndo™ Lite Linear Cutting Stapler and Loading Units for Single Use are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general abdominal, gynecologic, thoracic, and pediatric surgical procedures.

Device Description

The proposed device places two, triple-staggered rows of titanium staples and simultaneously divides the tissue from central line. The device is available in 260mm, 350mm and 440mm three lengths. The device is available in four five sizes to accommodate various tissue thickness: 2.0mm, 2.5mm, 3.5mm, 3.8mm and 4.1mm. The device may be reloaded and fired up to 13 times in a single procedure.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K172960
Product Name: easyEndo™ Universal Linear Cutting Stapler and Loading Units for Single Use

Predicate Device 2
510(k) Number: K080839
Product Name: ECHELON GRAY CARTRIDGE, MODEL ERC45M

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- USP 43-NF38:2020 <151> Pyrogen Test
- USP 42-NF 37<85> Bacterial Endotoxins Tests
- ASTM F88/F88M-15 Standard test method for seal strength of flexible barrier materials;
- ISO 11137-2:2013 Sterilization of health care products -Radiation- Part 2: Establishing the sterilization dose

Ex-vivo tissue test was conducted on porcine stomach and intestine tissue for both proposed device and predicate device to evaluate the device performance. The test items include Pressure Resistance Test, Closed Staple Dimension Test, Staple Formation Test and Force Required to Fire Stapler Test. Besides tissue test, jugular vein test was conducted on a porcine model to evaluate the device performance in thin tissues. This test was conducted on both proposed device and predicate device for less than 2.5mm staple height. Burst pressure, closed staple height and staple formation were evaluated in jugular vein test.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device 1 K172960	Predicate Device 2 K080839	Remark
Product Code	GDW&GAG	GDW&GAG	GDW	SE
Regulation Number	21 CFR 878.4750&21CFR 878.4800	21 CFR 878.4750&21CFR 878.4800	21 CFR 878.4750	SE
Intended Use	The easyEndo™ Lite Linear Cutting Stapler and Loading Units for Single Use are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general abdominal, gynecologic, thoracic, and pediatric surgical procedures.	The devices are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general abdominal, gynecologic, thoracic, and pediatric surgical procedures.	The Echelon Endoscopic Linear Cutters, Staplers and Reloads are intended for transection, resection, and/or anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.	Similar
Main Configuration	Stapler Knife Staple	Stapler Knife Staple	Knife Staple	Similar
Operate Principle	Manual	Manual	Manual	SE
Cutting mechanism	Linear	Linear	Linear	SE
Safety mechanism	Safety release for preventing from	Safety release for preventing from	Safety release for preventing from	SE

	mis-firing	mis-firing	mis-firing	
Suture Length	45mm, 60mm	45mm, 60mm	45mm	Similar
Staple Height	2.0mm, 2.5mm, 3.5mm, 3.8mm, 4.1mm	2.5mm, 3.5mm, 3.8mm, 4.1mm	2.0mm	Similar
Row Number of Staples	6	6	6	SE
Closed Staple Form				SE
Staple Material	Unalloyed Titanium	Unalloyed Titanium	Unalloyed Titanium	SE
Patient-contact material	Stainless steel (SUS304) Stainless steel (SUS420, 20Cr13) Stainless steel (17-4PH) Stainless steel (SUS301) Polyamide Unalloyed Titanium	Unalloyed Titanium Polyphthalamide + Glass Fiber Stainless Steel	Unalloyed Titanium	Different
Sterilization	Irradiation Sterilization	Irradiation Sterilization	EO sterilization	Different
Endotoxin Limit	20 EU	20 EU	20 EU	SE
Labeling	Conforms with 21 CFR 801	Conforms with 21 CFR 801	Conforms with 21 CFR 801	SE

Similar-Indication for use

The indication for use for proposed device is different from predicate device 2, the proposed device does not have the indication for using with buttressing material or organ transection and resection. However, the indication for use for proposed device can be covered by the predicate device 2. In addition, the indications for use for the proposed device is same as the predicate device 1. Therefore, this difference is not considered to affect substantially equivalence.

Similar-Structure

The structure for the proposed device is different from the predicate device 2 due the predicate device 2 is a cartridge. However, the structure for proposed device is same as the predicate device 1. Therefore, this difference is not considered to affect substantially equivalence.

Similar-Suture length

The proposed device has the additional suture length 60mm compared to predicate device. However, this suture length specification can be covered by the predicate device 1. Therefore, this difference is not considered to affect substantially equivalence.

Similar- Staple Height

The staple height of the proposed device is different from the predicate device 1 and predicate device 2. However, the staple height of the proposed device (2.5mm~4.1mm) can be covered by the predicate device 1 and the proposed staple height 2.0mm is same as predicate device 2. Therefore, this difference is not considered to affect substantially equivalence.

Different- Patient-contact material

The patient-contact material of the proposed device is different from the predicate device. However, the biocompatibility test has been performed on the material of the proposed device and the test result show that the material of the proposed device will not affect adverse effect on the patient. Therefore, this difference is not considered to affect substantially equivalence.

Different-Sterilization

The sterilization method for the proposed device is different from predicate device. However, the sterilization process has been validated per ISO 11137 and the validation result can demonstrate the sterilization parameter is validity which can maintain the declared sterilization assurance level, In addition, the irradiation sterilization method is also used for the predicate device 1. Therefore, this difference is not considered to affect substantially equivalence.

9. Substantially Equivalent (SE) Conclusion

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K172960 and K080839.