February 1, 2019

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

Re: K181657
Trade/Device Name: easyLC™ Linear Cutter Staplers and Loading Units for Single Use; easyCS™ Circular Stapler for Single Use
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: June 12, 2018
Received: June 22, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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

Digitally signed by David Krause -S
Date: 2019.02.01 10:39:52 -05'00'

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)*
K181657

Device Name
easyLCTM Linear Cutter Staplers and Loading Units for Single Use, easyCSTM Circular Stapler for Single Use

Indications for Use *(Describe)*
The easyLCTM Linear Cutter Staplers and Loading Units for Single Use have application in gastrointestinal for transection, resection, and/or creation of anastomoses.

The easyCSTM Circular Stapler for Single Use has applications throughout the alimentary for end to end, end to side and side to side 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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Exhibit #2 510(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: K181657

1. Date of Preparation: 12/29/2018

2. Sponsor Identification

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

Establishment Registration Number: Not yet registered.

Contact Person: Liang Xia
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3. Designated Submission Correspondent

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

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P.O. Box 120-119, Shanghai, 200120, China

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4. Identification of Proposed Device

Trade Name: easyLC™ Linear Cutter Staplers and Loading Units for Single Use
easyCS™ Circular Stapler 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

Intended Use Statement:

The easyLC™ Linear Cutter Staplers and Loading Units for Single Use have application in gastrointestinal for transection, resection, and/or creation of anastomoses.

The easyCS™ Circular Stapler for Single Use has applications throughout the alimentary for end to end, end to side and side to side anastomoses.

Device Description

The easyLC™ Linear Cutter Staplers and Loading Units for Single Use place two double staggered rows of titanium staples and simultaneously cut and divides tissue between the two double rows. The device is available in 60mm, 80mm and 100mm length with reload in 2.5mm, 3.8mm and 4.8mm staple size to accommodate various tissue thicknesses. The device may be reloaded and fired up to 8 times in a single procedure.

The easyCS™ Circular Stapler for Single Use places a double staggered, circular row of titanium staples upon activation, which was achieved by squeezing the handles firmly as far as they could go. Immediately after formation of the staples, the excess tissue will be resect by the circular knife, and then a circular anastomosis is created. The stapler is available in 21mm, 25mm, 29mm, 31mm and 33mm

five specifications. Two staple sizes (3.5mm and 4.8mm) are available to accommodate various tissue thicknesses.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K020779
Product Name: ENDOPATH™ and PROXIMATE™ Linear Cutters and Staplers

Predicate Device 2
510(k) Number: K983536
Device Name: PROXIMATE Curved and Straight Intraluminal Staplers

Predicate Device 3
510(k) Number: K100723
Device Name: PROXIMATE Curved and Straight Intraluminal Staplers

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 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009 Biological evaluation of medical 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
- USP 38-NF 33 <85> Bacterial Endotoxins Tests
- ASTM F 88/F88M-09 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
- USP 39-NF 34 <151> Pyrogen

Bench test was conducted on porcine stomach and intestine tissue for both proposed device and predicate device to determine substantially equivalence. The bench tests include following tests

- Pressure Resistance Test
- Closed Staple Dimension Test
- Staple Formation Test

- Force Required to Fire Stapler Test

Biocompatibility test was conducted on the proposed device, the test include cytotoxicity, irritation, skin sensitization and pyrogenicity.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison for easyLC™ Linear Cutter Staplers and Loading Units for Single Use

Item	Proposed Device	Predicate Device 1 K020779
Product Code	GDW	GDW
Regulation Number	21 CFR 878.4750	21 CFR 878.4750
Intended Use	The easyLC™ Linear Cutter Staplers and Loading Units for Single Use have application in gastrointestinal for transection, resection, and/or creation of anastomoses.	The PROXIMATE Linear and Vascular Linear Cutters with Safety Lockout have application in gastrointestinal, gynecologic, thoracic and pediatric surgery for transection, resection, and/or creation of anastomoses and can be used with staple line or tissue buttressing materials, such as bovine pericardium
Cutting Mechanism	Linear	Linear
Operation Principle	Manual	Manual
Safety Mechanism	Safety release for prevent from mis-firing	Safety release for prevent from mis-firing
Suture Length	60mm, 80mm, 100mm	55, 75mm
Closed Staple Height	1.0mm, 1.5mm, 2.0mm	1.0mm, 1.5mm, 1.8mm, 2.0mm
Closed staple form		
Endotoxin Limit	20 EU	Same
Labeling	Conforms with 21 CFR 801	Conforms with 21 CFR 801

Table 2 Comparison for easy CS™ Circular Stapler for Single Use

Item	Proposed Device	Predicate Device 2 K983536	Predicate Device 3 K100723
Product Code	GDW	GDW	GDW
Regulation Number	21 CFR 878.4750	21 CFR 878.4750	21 CFR 878.4750
Intended Use	The easyCS™ Circular Stapler for Single Use has applications throughout the alimentary for end to end, end to side and side to side anastomoses.	The PROXIMATER Curved and Straight Intraluminal Staplers have application throughout the alimentary for end to end, end to side and side to side anastomoses.	The Disposable Circular Stapler has application throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses.
Cutting Mechanism	Circular Knife	Circular Knife	Circular Knife
Operation Principle	Manual	Manual	Manual
Safety Mechanism	Safety Release is used for preventing from mis-firing.	Safety Release is used for preventing from mis-firing.	Safety Release is used for preventing from mis-firing.
Diameter	21mm, 25mm, 29mm, 31mm, 33mm	21mm, 25mm, 29mm, 33mm	25.5mm, 29.5mm
Closed Staple Height	1.0~2.5mm	1.0~2.5mm	1.5~2.0mm
Closed staple form			
Endotoxin Limit	20 EU	20EU	20EU
Labeling	Conforms with 21 CFR 801	Conforms with 21 CFR 801	Conforms with 21 CFR 801

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.