DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 18, 2018

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

Re: K181620
Trade/Device Name: Endoscopic Linear Cutting Staplers and Loading Units for Single Use
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: June 7, 2018
Received: June 20, 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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)*
K181620

Device Name
Endoscopic Linear Cutting Staplers and Loading Units for Single Use

Indications for Use *(Describe)*
The device is 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.

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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Tab #7 510(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: K181620

1. Date of Preparation: 04/16/2018

2. Sponsor Identification

Ezisurg (Suzhou) Medical Co., Ltd.
Building 16, No.8 Jinfeng Rd., Suzhou National Hi-Tech District, Suzhou 215163 Jiangsu, China

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3. Designated Submission Correspondent

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

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4. Identification of Proposed Device

Trade Name: Endoscopic Linear Cutting Staplers and Loading Units 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 device is 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 70mm, 160mm and 250mm three lengths. Reloads of Endoscopic Linear Cutting Staplers and Loading Units for Single Use are available in in five staple sizes to accommodate various tissue thickness: 2.5mm, 3.5mm, 3.8mm, 4.1mm and 4.8mm. The device may be reloaded and fired up to 25 times for 1 firing in a single procedure.

5. Identification of Predicate Device

Predicate Device 1
510(k) Number: K111825
Product Name: Endo GIA™ Staplers

Predicate Device 2
510(k) Number: K061156
Device Name: ENDOPATH Linear Cutters and 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-NF34:2016 <151> Pyrogen Test

The tests provided in this submission include package integrity test, bacteria endotoxin test, biocompatibility test, shelf life test and performance test were performed on both proposed device and predicate device to determine substantial equivalence, the performance test include following items

- Firing Force Test
- Staple Formation Test
- Staple Line Pressure Test
- Staple Line Tensile Test
- Hemostasis Evaluation Test
- Close Staple Height Test

Biocompatibility tests included cytotoxicity, sensitization, intracutaneous irritation and pyrogenicity.

Shelf life testing which included package integrity and performance evaluations were performed.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison for Endoscopic Linear Cutting Staplers and Loading Units for Single Use

Item	Proposed Device	Predicate Device 1 K111825	Predicate Device 2 K061156
Product Code	GDW	GDW	GDW
Regulation Number	21 CFR 878.4750	21 CFR 878.4750	21 CFR 878.4750
Intended Use	The device 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 Endo GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.	The ENDOPATH Endocutter 60 Endoscopic Linear Cutter is intended for transection, resection, and/or creation of anastomoses. The instrument has application in multiple open minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. It can be used with staple line or tissue buttressing materials.
Cutting Mechanism	Linear	Linear	Linear
Operation Principle	Manual	Manual	Manual
Safety Mechanism	Green button is used for preventing from mis-firing.	Green button is used for preventing from mis-firing.	Green button is used for preventing from mis-firing.
Suture Length	30mm, 45mm, 60mm	30mm, 45mm, 60mm	60mm
Staple height	2.5mm, 3.5mm, 3.8mm, 4.1mm, 4.8mm	2.0mm, 2.5mm, 3.5mm, 4.8mm	2.5mm, 3.5mm, 3.8mm, 4.1mm
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.