February 11, 2019

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

Re: K183477
Trade/Device Name: easyPPHTM Hemorrhoidal Stapler for Single Use
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: November 6, 2018
Received: December 17, 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: 2019.02.11 09:02:04 -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)*
K183477

Device Name
easyPPHTM Hemorrhoidal Stapler for Single Use

Indications for Use *(Describe)*
The easyPPHTM Hemorrhoidal Stapler for Single Use has application throughout the anal canal to perform surgical treatment of hemorhoidal disease.

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: K183477

1. Date of Preparation: 1/28/2019

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: 3014264910

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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

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Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: easyPPH™ Hemorrhoidal Stapler for Single Use
Common Name: Stapler and Reload
Size: PPH33

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 easyPPH™ Hemorrhoidal Stapler for Single Use has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

Device Description:

The easyPPH™ Hemorrhoidal Stapler 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 33mm length with 3.5mm staple size.

5. Identification of Predicate Device

510(k) Number: K030411
Product Name: PROXIMATE®PPH Hemorrhoidal Circular Stapler and Accessories

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 provided in this submission include

package integrity test, bacteria endotoxin test, biocompatibility tests. The shelf life test and performance tests 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
- Closed Staple Height Test

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

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;
- ASTM F 1929
- ISO 11137-2:2013 Sterilization of health care products -Radiation- Part 2: Establishing the sterilization dose
- USP 39-NF 34 <151> Pyrogen

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison for easyPPH™ Hemorrhoidal Stapler for Single Use

Item	Proposed Device	Predicate Device
Product Code	GDW	GDW
Regulation Number	21 CFR 878.4750	21 CFR 878.4750
Intended Use	The easyPPH™ Hemorrhoidal Stapler for Single Use has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.	The PROXIMATE® PPH Hemorrhoidal Circular Stapler and accessories have application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.
Cutting Mechanism	Circular	Circular
Operation Principle	Manual	Manual
Safety Mechanism	Safety release for prevent from mis-firing	Safety release for prevent from mis-firing
Staple size	3.5mm	3.5mm
Closed Staple Height	1.0-1.6mm	1.0-1.6mm
Closed staple form		
Endotoxin Limit	20 EU	20EU
Labeling	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.