DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 29, 2015

EziSurgMedical Company, Ltd.
% Ms. Diana Hong
Mid-Link Consulting Company, Ltd.
P.O. Box 120-119
200120 Shanghai
China

Re: K143129
Trade/Device Name: easyEndo® 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: October 29, 2014
Received: October 31, 2014

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143129

Device Name

easyEndo® Linear Cutting Stapler and Loading Unit for Single Use

Indications for Use *(Describe)*

The easyEndo® Linear Cutting Stapler and Loading Unit for Single Use have applications in abdominal, gynecologic and pediatric surgery for resection, transection, and creation of 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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Tab #7 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation: 10/24/2014

2. Sponsor Identification

EziSurg Medical Co., Ltd.
Room 312, Bldg. 2, No. 1690, Cailun Road
Zhangjiang High-Tech Park
Pudong, Shanghai, 201203, P.R. China

Establishment Registration Number: Not yet registered

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

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

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: easyEndo® Linear Cutting Stapler and Loading Unit for Single Use
Common Name: Stapler
Model:
Stapler F12S, F12M, F12L
Loading Unit FDU 45W, FDU 45B, FDU 45G, FDU 60B, FDU 60G

Regulatory Information

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

Intended Use Statement:
The easyEndo® Linear Cutting Stapler and Loading Unit for Single Use have applications in abdominal, gynecologic and pediatric surgery for resection, transection, and creation of anastomoses.

Device Description

The proposed devices, easyEndo® Linear Cutting Stapler and Loading Unit for Single Use, are sterilized and disposable surgical instruments, which have applications in abdominal, gynecologic and pediatric surgery for resection, transection, and creation of anastomoses.

It places two, triple-staggered rows of titanium staples and simultaneously divides the tissue from central line. The easyEndo® Linear Cutting Stapler may be reloaded and fired no more than 25 times in a single procedure.

5. Identification of Predicate Device

510(k) Number: K120258
Product Name: Endo GIA™ Universal Staplers with Duet TRS™ reloads

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:

- ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.

- ASTM 1929-12, Standard Test Method For Detecting Seal Leaks In Porous Medical Packaging By Dye Penetration.
- USP 37-NF32:2014, <85> Bacterial Endotoxins Test
- USP 37-NF32 <151> Pyrogen Test (USP Rabbit Test)
- ISO 10993-5,2009/(R) 2014:Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The easyEndo® Linear Cutting Stapler and Loading Unit for Single Use have applications in abdominal, gynecologic and pediatric surgery for resection, transection, and creation of anastomoses.	Similar
Cutting Mechanism	Linear	Same
Operation Principle	Manual	Same
Safety Machanism	Green button for preventing from mis-firing.	Same
Suture Length	45,60 mm	Same
Closed Staples Height	1.0, 1.5, 2.0 mm	Same
Closed Staples Form		Same
Patient-contact Material	Unalloyed Titanium conforms to ASTM F 67, Polyamide resin	Similar
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Similar
Endotoxin Limit	20 EU per Product	Same
Labeling	Conforms to 21 CFR part 801	Same

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.