March 3, 2022

Wuxi Beien Surgery Device Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K211811
Trade/Device Name: Disposable Endoscopic Staplers and Reload Unit, Disposable Hemorrhoidal Cutter Staplers, Disposable Linear Cutter Staplers, Disposable Circular Staplers
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: January 25, 2022
Received: January 26, 2022

Dear Diana 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,

Mark Trumbore
Assistant Director
DHT4A: Division of General 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)*
K211811

Device Name
Disposable Endoscopic Staplers and Reload Unit, Disposable Hemorrhoidal Cutter Staplers, Disposable Linear Cutter Staplers

Indications for Use *(Describe)*
The Disposable circular staplers have application throughout the alimentary tract for end to end, end to side, and side to side anastomoses.

The Disposable Endoscopic Staplers and Reload Unit have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses.

The Disposable Hemorrhoidal Cutter Staplers have application for general treatment of hemorrhoids.

Disposable Linear Cutter Staplers have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the 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.

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Tab # 6 510(k) Summary

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

The assigned 510(k) Number: K211811

1. Date of Preparation: 03/03/2022

2. Sponsor Identification

Wuxi Beien Surgery Device Co., Ltd.
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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: Disposable Endoscopic Staplers and Reload Unit
Disposable Hemorrhoidal Cutter Staplers
Disposable Linear Cutter Staplers
Disposable Circular Staplers
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: II
Product Code: GAG;
Regulation Number: 21 CFR 878.4800
Review Panel: General & Plastic Surgery

Indications for Use:

The Disposable circular staplers have application throughout the alimentary tract for end to end, end to side, and side to side anastomoses.

The Disposable Endoscopic Staplers and Reload Unit have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses.

The Disposable Hemorrhoidal Cutter Staplers have application for general treatment of hemorrhoids.

Disposable Linear Cutter Staplers have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the creation of anastomoses.

Device Description:

Disposable circular staplers place 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 are available in 23mm, 29mm, 32mm and 34mm four specifications. The staple height is 4.8mm.

Disposable Endoscopic Staplers and Reload Unit place two, triple-staggered rows of progressive titanium staples and simultaneously divides the tissue from central line. The devices are available in 30mm, 45mm and 60mm three lengths. Reloads are available in 2.5mm, 3.5mm, 4.0mm, 4.8mm four staple sizes and 3.0~4.0, 4.0~5.0 two progressive staple sizes to accommodate various tissue thicknesses. The device may be reloaded and fired up to 10 times in a single procedure.

Disposable Hemorrhoidal Cutter Staplers are a set of instruments that place a double staggered, circular row of titanium staples. Immediately after the formation of staples, the circular knife blade resects the excess of compressed mucosa. The stapler is available in 32mm, 34mm two specifications. The staple size is 4.0mm. It cannot be reloaded.

Disposable Linear Cutter Staplers place two double staggered rows of titanium staples and simultaneously cut and divides tissue between the two double rows. The devices are available in 60mm, 80mm and 100mm lengths. Reloads are available in two staple sizes to accommodate various tissue thicknesses: 3.8mm and 4.8mm. It may be reloaded and fired up to 5 times in a single procedure.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K120179
Product Name: Circular Staplers with Staples
Linear Cutting Staplers with Single Use Loading Units
Endoscopic Linear Cutting Staplers with Single Use Loading Units
Manufacturer: Reach Surgical, Inc.

Predicate Device 2
510(k) Number: K161757
Product Name: Single Use Hemorrhoidal Staplers
Single Use Endoscopic Linear Cutters and Reloads
Manufacturer: Victor Medical Instruments Co., Ltd

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 device- Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009 Biological evaluation of medical Devices-Part 5: Test for in vitro cytotoxicity.
- ISO10993-10:2010 Biological evaluation of medical devices-Part 10: Test for irritation and delayed-type hypersensitivity.
- USP 43-NF 38 <85> Bacterial Endotoxins Test
- ASTM F 88/F88M-15 Standard test method for seal strength of flexible barrier materials;
- ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
- USP 43-NF 38 <151> Pyrogen
- ISO 10993-11:2017 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

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 2.5mm staple height. Burst pressure, closed staple height and staple formation were evaluated in jugular vein test.

Biocompatibility test was conducted on the proposed device, the test performed on the device includes cytotoxicity, irritation, skin sensitization acute toxicity test and pyrogenicity. Genotoxicity and implantation were evaluated for the permanent contact staple. In addition, chemical characterization was performed on the staple to evaluate the leachable substance and toxicological risk was assessed for the characterized substance.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison for the Disposable Circular Staplers

Item	**Proposed Device**	**Predicate Device 1** K120179
Product Code	GDW	GDW
Regulation Number	21 CFR 878.4750	21 CFR 878.4750
Class	II	II
Indication for Use	The Disposable circular staplers have application throughout the alimentary tract for end to end, end to side, and side to side anastomoses.	The Circular Staplers with Staples have applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoseopic surgeries.
Cutting Mechanism	Circular Knife	Circular Knife
Operation Principle	Manual	Manual
Safety Mechanism	Safety Release is used for preventing from mis-firing	Safety Release is used for preventing from mis-firing
Specification	23, 29, 32, 34	17, 23, 25,28, 32, 34
Staple Height	4.8mm	3.5mm, 4.8mm
Closed staple form		
Endotoxin Limit	20EU	20EU
Labeling	Conforms with 21CFR 801	Conforms with 21CFR 801

Table 2 Comparison for Disposable Linear Cutter Staplers

Item	**Proposed Device**	**Predicate Device 1** K120179
Product Code	GDW	GDW
Regulation Number	21 CFR 878.4750	21 CFR 878.4750
Class	II	II
Indication for Use	Disposable Linear Cutter Staplers have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the creation of anastomoses.	The Linear Cutting Staplers with Single Use Loading Units have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection, and the creation of anastomoses.
Cutting Mechanism	Linear Knife	Linear Knife
Operation Principle	Manual	Manual
Safety Mechanism	Safety Release is used for preventing from mis-firing	Safety Release is used for preventing from mis-firing
Suture Length	60,80,100mm	60mm,80mm,100mm
Closed Staple height	3.8mm, 4.8mm	3.8mm, 4.8mm
Closed staple form		
Endotoxin Limit	20EU	20EU
Labeling	Conforms with 21CFR 801	Conforms with 21CFR 801

Table 3 Comparison for the Disposable Endoscopic Staplers and Reload Unit

Item	**Proposed Device**	**Predicate Device 1** K120179	**Predicate Device 2** **K161757**
Product Code	GDW	GDW	GDW
Regulation Number	21 CFR 878.4750	21 CFR 878.4750	21 CFR 878.4750
Class	II	II	II
Indication for Use	The Disposable Endoscopic Staplers and Reload Unit have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses.	The Endoseopic Linear Cutting Staplers with Single Use Loading Units have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.	The Single Use Endoscopic Linear Cutters and Reloads can be used in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of side-to-side anastomosis.
Cutting Mechanism	Linear Knife	Linear Knife	Linear 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.	Green button is used for preventing from mis-firing.
Suture Length	30mm,45mm,60mm	30mm,45mm,60mm	30mm,45mm,60mm
Staple height	2.5mm, 3.5mm, 4.0mm, 4.8mm, 3.0~4.0mm, 4.0~5.0mm	2.0mm, 2.5mm, 3.5mm, 4.0mm, 4.8mm	2.0~3.0mm, 3.0~4.0mm, 4.0~5.0mm
Closed staple form			
Endotoxin Limit	20EU	20EU	20EU
Labeling	Conforms with 21CFR 801	Conforms with 21CFR 801	Conforms with 21CFR 801

Table 4 Comparison for the Disposable Hemorrhoidal Cutter Staplers

Item	**Proposed Device**	**Predicate Device 2** K161757
Product Code	GDW	GDW
Regulation Number	21 CFR 878.4750	21 CFR 878.4750
Class	II	II
Indication for Use	The Disposable Hemorrhoidal Cutter Staplers have application for general treatment of hemorrhoids.	The Single Use Hemorrhoidal Staplers have application for general treatment of hemorrhoids.
Cutting Mechanism	Circular Knife	Circular Knife
Operation Principle	Manual	Manual
Safety Mechanism	Safety Release is used for preventing from mis-firing.	Safety Release is used for preventing from mis-firing.
Specification	32, 34	32, 34
Staple Height	4.0mm	4.0mm
Closed staple form		
Endotoxin Limit	20EU	20EU
Labeling	Conforms with 21CFR 801	Conforms with 21CFR 801

9. Substantially Equivalent (SE) Conclusion

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