May 27, 2021

Beijing Biosis Healing Biological Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K201639
Trade/Device Name: Disposable Circular Stapler, Disposable Hemorrhoidal Stapler, Disposable Linear Stapler and Reloads, Disposable Linear Cutter Stapler and Reloads, Disposable Endoscopic Linear Cutter Stapler and Reloads

Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: June 2, 2020
Received: June 16, 2020

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,

for Cindy Chowdhury, Ph.D., MBA
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K210639

Device Name
Disposable Circular Stapler; Disposable Hemorrhoidal Stapler; Disposable Linear Stapler and Reloads; Disposable Linear Cutter Stapler and Reloads; Disposable Endoscopic Linear Cutter Stapler and Reloads

Indications for Use *(Describe)*
The Disposable Circular Stapler has application throughout the alimentary tract to create end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

The Disposable Hemorrhoidal Circular Stapler has application throughout the anal canal to perform surgical treatment of hemorrhoid disease.

The Disposable Linear Stapler and Reloads can be applied in abdominal, thoracic and pediatric surgical procedures for transection or resection of tissue.

The Disposable Linear Cutter Stapler and Reloads can be applied in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.

The Disposable Endoscopic Linear Cutter Stapler and Reloads has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transaction and creation of anastomosis.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: K201639

1. Date of Preparation: 05/27/2021

2. Sponsor Identification

Beijing Biosis Healing Biological Technology Co., Ltd.
No.6 Plant West, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600, Beijing, China

Establishment Registration Number: 3016668451

Contact Person: Jiali Zhou
Position: RA
Tel: +86-10-61252660
Fax: +86-10-61252030
Email: zhoujiali@biosishealing.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Huifan Wang (Alternative Contact Person)

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

Tel: +86-21-22815850
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name:
Disposable Circular Stapler
Disposable Hemorrhoidal Stapler
Disposable Linear Stapler and Reloads
Disposable Linear Cutter Stapler and Reloads
Disposable Endoscopic Linear Cutter Stapler and Reloads
Common Name: Stapler, Implantable

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

Indications for Use:

The Disposable Circular Stapler has application throughout the alimentary tract to create end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

The Disposable Hemorrhoidal Circular Stapler has application throughout the anal canal to perform surgical treatment of hemorrhoid disease.

The Disposable Linear Stapler and Reloads can be applied in abdominal, thoracic and pediatric surgical procedures for transection or resection of tissue.

The Disposable Linear Cutter Stapler and Reloads can be applied in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.

The Disposable Endoscopic Linear Cutter Stapler and Reloads has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transaction and creation of anastomosis.

Device Description:

Disposable Circular Stapler 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 are available in 25mm, 26mm, 28mm, 29mm and 32mm five

specifications. The staple is available in 4.5mm and 4.8mm two different heights.

Disposable Endoscopic Linear Cutter Stapler and Unit places two, triple-staggered rows of titanium staples and simultaneously divides the tissue from central line. The devices are available in 30mm, 45mm and 60mm three specifications. Reloads are available in 2.5mm, 3.5mm, 4.0mm and 4.8mm four staple sizes to accommodate various tissue thicknesses. The device may be reloaded and fired up to 25 times in a single procedure.

Disposable Hemorrhoidal Stapler is 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 are available in 32mm, 33mm and 34mm three specifications. The staple size is 3.8mm. It cannot be reloaded.

Disposable Linear Cutter Staplers and Reload places two double staggered rows of titanium staples and simultaneously cut and divides tissue between the two double rows. The devices are available in 55mm, 60mm, 75mm, 80mm and 100mm five specifications. 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 8 times in a single procedure.

The Disposable Linear Stapler and Reload places a double staggered row of titanium staples and is available in 30mm, 45mm, 60mm and 90mm four specifications for use in various applications. Two staple sizes (3.5mm and 4.8mm) are available to accommodate various tissue thicknesses. It may be reloaded and fired up to 8 times in a single procedure.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K103470
Product Name: PANTHER Group of Surgical Staplers

Predicate Device 2
510(k) Number: K142577
Product Name: Panther Endo Linear Cutter Staplers with Single Use Loading Unit

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
- USP42-NF37 <85> Bacterial Endotoxins Tests
- ASTM F 88/F88M-15 Standard test method for seal strength of flexible barrier materials;
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

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.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Disposable Circular Stapler

Item	Proposed Device	Predicate Device 1 K103470
Product Code	GDW	GDW
Regulation No.	878.4750	878.4750
Indication for Use	The Disposable Circular Stapler has application throughout the alimentary tract to create end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries	The Panther circular staplers and accessories have application throughout the alimentary tract to create end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries
Main Configuration	Anvil Cartridge Drivepipe Firing Handle Insurance Rating Nut Staple Circular Knife Cartridge Cover	Anvil Cartridge Drivepipe Firing Handle Insurance Rating Nut Staple Circular Knife Cartridge Cover
Operate Principle	Manual	Manual
Cutting Mechanism	Circular Knife	Circular Knife
Safety Mechanism	Insurance is used for preventing from mis-firing	Insurance is used for preventing from mis-firing
Specification	25, 26, 28, 29 and 32mm	24, 26, 29, 32 and 34mm
Staple Height	4.5 and 4.8mm	4.5 and 4.8mm
Row number of Staple	2	2
Closed Staple form	B-shape	B-shape
Staple material	Unalloyed Titanium	Unalloyed Titanium
Patient-contact material of stapler	Stainless Steel ABS AL6063	Unknown
Sterilization	Ethylene Oxide	Ethylene Oxide
Endotoxin Limit	20EU	20EU
Labeling	Conforms with 21 CFR 801	Conforms with 21 CFR 801

Table 2 Comparison of Disposable Hemorrhoidal Stapler

Item	Proposed Device	Predicate Device 1 K103470
Product Code	GDW	GDW
Regulation No.	878.4750	878.4750
Indication for Use	The Disposable Hemorrhoidal Circular Stapler has application throughout the anal canal to perform surgical treatment of hemorrhoid disease	The PANTHER Hemorrhoidal Circular Stapler and accessories have application throughout the anal canal to perform surgical Treatment of hemorrhoidal disease.
Main Configuration	Anvil Cartridge Cover Cartridge Fixed handle Firing Handle Rating Nut Insurance Staple Circular Knife	Anvil Cartridge Cover Cartridge Fixed handle Firing Handle Rating Nut Insurance Staple Circular Knife
Operate Principle	Manual	Manual
Cutting Mechanism	Circular Knife	Circular Knife
Safety Mechanism	Insurance is used for preventing from mis-firing	Insurance is used for preventing from mis-firing
Specification	32, 33 and 34mm	31, 32, 33 and 34mm
Staple Height	3.8mm	3.8mm
Row number of Staple	2	2
Closed Staple form	B-shape	B-shape
Staple material	Unalloyed Titanium	Unalloyed Titanium
Patient-contact material of stapler	Stainless Steel PE ABS PC	Unknown
Sterilization	Ethylene Oxide	Ethylene Oxide
Endotoxin Limit	20EU	20EU
Labeling	Conforms with 21 CFR 801	Conforms with 21 CFR 801
Sterilization	Ethylene Oxide	Ethylene Oxide

Table 3 Comparison of Disposable Linear Stapler and Reloads

Item	Proposed Device	Predicate Device 1 K103470
Product Code	GDW	GDW
Regulation No.	878.4750	878.4750
Indication for Use	The Disposable Linear Stapler and Reloads can be applied in abdominal, thoracic and pediatric surgical procedures for transection or resection of tissue.	The PANTHER Linear Stapler can be applied in abdominal, thoracic and pediatric surgical procedures for transection or resection of tissue.
Main Configuration	Anvil Reloading Unit Left and right slider Rest knob Fixed handle Firing handle	Anvil Reloading Unit Left and right slider Rest knob Fixed handle Firing handle
Operate Principle	Manual	Manual
Suture length	30 mm, 45 mm, 60 mm and 90 mm	30mm, 45mm, 60mm, 75mm and 90mm
Staple Height	3.5mm and 4.8mm	2.5mm, 3.5mm and 4.8mm
Row number of Staple	Double staggered rows	Double staggered rows
Closed Staple form	B-shape	B-shape
Staple material	Unalloyed Titanium	Unalloyed Titanium
Patient-contact material of stapler	PC Stainless Steel PA-757	Unknown
Sterilization	Ethylene Oxide	Ethylene Oxide
Endotoxin Limit	20EU	20EU
Labeling	Conforms with 21 CFR 801	Conforms with 21 CFR 801

Table 4 Comparison of Disposable Linear Cutter Stapler and Reloads

Item	Proposed Device	Predicate Device 1 K103470
Product Code	GDW	GDW
Regulation No.	878.4750	878.4750
Indication for Use	The Disposable Linear Cutter Stapler and Reloads can be applied in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis	The PANTHER Linear Cutter Stapler can be applied in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.
Main Configuration	Push Button Rotating pin Cutting knife Cartridge cover Cartridge	Push Button Rotating pin Cutting knife Cartridge cover Cartridge
Operate Principle	Manual	Manual
Cutting Mechanism	Linear knife	Linear knife
Suture length	55mm, 60 mm, 75mm, 80 mm and 100 mm	55mm, 60mm, 75mm, 80mm, 100mm and 110mm
Staple Height	3.8mm and 4.8mm	3.8mm and 4.8mm
Row number of Staple	two double staggered mows	two double staggered mows
Closed Staple form	B-shape	B-shape
Staple material	Titanium	Titanium
Patient-contact material of stapler	Stainless Steel PC ABS POM PPA	Unknown
Sterilization	Ethylene Oxide	Ethylene Oxide
Endotoxin Limit	20EU	20EU
Labeling	Conforms with 21 CFR 801	Conforms with 21 CFR 801

Table 5 Comparison of Disposable Endoscopic Linear Cutter Stapler and Reloads

Item	Proposed Device	Predicate Device 2 K142577
Product Code	GDW	GDW
Regulation No.	878.4750	878.4750
Indication for Use	Disposable Endoscopic Linear Cutter Stapler and Reloads has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transaction and creation of anastomosis.	PANTHER Endo Linear Cutter Stapler with Single Use Loading Units has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transaction and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.
Main Configuration	Firing rod Barrel shell Rotary knob Insurance button Left and right shell Cartridge	Firing rod Barrel shell Rotary knob Insurance button Left and right shell Cartridge
Operate Principle	Manual	Manual
Cutting Mechanism	Linear Knife	Linear Knife
Safety Mechanism	Insurance button for preventing from miss-firing	Insurance button for preventing from miss-firing
Suture length	30mm, 45mm and 60mm	30mm, 45mm and 60mm
Staple Height	2.5, 3.5, 4.0 and 4.8mm	2.0, 2.5, 3.5, 4.0 and 4.8mm
Row number of Staple	Two, triple-staggered rows	Two, triple-staggered rows
Closed Staple form	B-shape	B-shape
Staple material	Unalloyed Titanium	Unalloyed Titanium
Patient-contact material of stapler	PPA Stainless Steel	Stainless steel Polymeric materials Adhesives lubricants
Sterilization	Ethylene Oxide	Ethylene Oxide
Endotoxin Limit	20EU	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.