Ningbo VeryKind Medical Device Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K211458
Trade/Device Name: Disposable Anorectal Staplers, Disposable Linear Cutting Staplers, Disposable Endoscopic Cutting Staplers
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: November 25, 2021
Received: November 29, 2021

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,

Dr. Mark Trumbore, Ph.D.
Assistant Director for Robotically-Assisted Surgical Devices Team
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

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)*
K211458

Device Name
Disposable Anorectal Staplers; Disposable Linear Cutting Staplers; Disposable Endoscopic Cutting Staplers

Indications for Use *(Describe)*
The Disposable Anorectal Staplers have application for general treatment of hemorrhoids.

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

The Disposable Endoscopic Cutting Staplers 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.

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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: K211458

1. Date of Preparation: 12/30/2021

2. Sponsor Identification

Ningbo VeryKind Medical Device Co., Ltd.
#100 Jinghua Road, High-tech Industrial Development Zone, Ningbo 315040 Zhejiang,P.R. China

Establishment Registration Number: Not registered yet.

Contact Person: Pengfei Hong
Position: QA Manager
Tel: +86-15888523540
Fax: +86-574-87910572
Email: pfhong@nbverkind.com

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

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

4. Identification of Proposed Device

Trade Name: Disposable Anorectal Staplers;
Disposable Linear Cutting Staplers;
Disposable Endoscopic Cutting Staplers

Common Name: Stapler, implantable

Regulatory Information
Classification Name: Staple, Implantable
Classification: II;
Product Code: GDW
Regulation Number: 21CFR 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

Indication for Use:
The Disposable Anorectal Staplers have application for general treatment of hemorrhoids.

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

The Disposable Endoscopic Cutting Staplers has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transaction and creation of anastomosis.

Device Description:
The Disposable Anorectal 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 are available in 33mm. The staple size is 4.0mm. It cannot be reloaded.

The Disposable Linear Cutting Stapler places two double-staggered rows of titanium staples and simultaneously cut and divides tissue between the two double rows. The Disposable Linear Cutting Staplers is available in 60mm, 80mm and 100mm three specifications, and in two staple sizes 3.8mm and 4.8mm, to accommodate various tissue thickness. Each Disposable Linear Cutting Staplers may be reloaded up to 10 times in a single procedure.

The Disposable Endoscopic Cutting Stapler 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 lengths. Reloads are available in four staple sizes to accommodate various tissue thicknesses: 2.5mm, 3.5mm, 4.0mm and 4.8mm. The device may be reloaded and fired up to 10 times in a single procedure.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K161757
Product Name: Single Use Hemorrhoidal Staplers, Single Use Linear Cutters and Reloads

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

6. Reference Device

510(k) Number: K202709
Product Name: Disposable Powered Endoscopic Linear Cutting Staplers and Cartridges

7. Summary of Technological characteristics

Table 1 Technological Characteristics Comparison of Disposable Anorectal Staplers

ITEM	Proposed Device	Predicate Device 1 K161757	Remark
Product Code	GDW	GDW	Same
Regulation No.	878.4750	878.4750	Same
Class	II	II	Same
Indication for Use	The Disposable Anorectal Staplers have application for general treatment of hemorrhoids.	The Single Use Hemorrhoidal Staplers have application for general treatment of hemorrhoids.	Same
Main Configuration	Staple Knife Stapler	Staple Knife Stapler	Same
Operate Principle	Manual	Manual	Same
Cutting Mechanism	Circular Knife	Circular Knife	Same

Safety Mechanism	Safety release for preventing from mis-firing	Safety release for preventing from mis-firing	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Diameter (mm)	33mm	32mm, 34mm	Different
Staple Height (mm)	4.0mm	4.0mm	Same
Row number of Staple	2	2	Same
Closed Staple form	B-shape	B-shape	Same
Staple material	Unalloyed Titanium	Unalloyed Titanium	Same
Patient-contact material	Unalloyed Titanium Acrylonitrile-Butadiene-styrene Stainless Steel Polycarbonate Polyamide (nylon) Poly (ether sulfones)	Unalloyed Titanium Acrylonitrile-Butadiene-Styrene Stainless Steel	Different
Sterilization	EO sterilization	Irradiation Sterilization	Different
Endotoxin Limit	20EU	20EU	Same
Biocompatibility			
Cytotoxicity Test	No cytotoxicity	Comply with ISO 10993	Same
Sensitization Test	No sensitization		
Instracutaneous Test	No irritation		
System Toxicity Test	No systemic toxicity		
Pyrogen Test	No pyrogen		

Different- Diameter

The diameter of the proposed device is different from the predicate device. However, the diameter of the proposed device is within the range of that of the predicate device. Therefore, the difference will not raise any safety issues.

Different- Patient-contact material

The patient-contact material of the proposed device is different from the predicate device. However, the biocompatibility test has been conducted on the proposed device and the test result showed that the material of the proposed device does not have any adverse effect.

Different- Sterilization

The sterilization method of the proposed device is different from the predicate device. However, the sterilization process has been validated per ISO 11135 and the validation result showed that the sterilization method is effective.

Table 2 Technological Characteristics Comparison of Disposable Linear Cutting Staplers

ITEM	Proposed Device	Predicate Device 1 K161757	Remark
Product Code	GDW	GDW	Same
Regulation No.	878.4750	878.4750	Same
Class	II	II	Same
Indication for Use	The Disposable Linear Cutting Staplers have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection and the creation of anastomoses.	The Single Use Linear Cutters and Reloads have application in abdominal, gynecological, thoracic and pediatric surgery transection, resection and the creation of anastomoses.	Same
Main Configuration	Staple Knife Stapler	Staple Knife Stapler	Same
Operate Principle	Manual	Manual	Same
Cutting Mechanism	Linear knife	Linear knife	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Suture length (mm)	60mm, 80mm and 100mm	60mm, 80mm and 100mm	Same
Staple Height (mm)	3.8mm and 4.8mm.	3.8mm and 4.8mm.	Same
Row number of Staple	4	4	Same
Closed Staple form	B-shape	B-shape	Same
Staple material	Unalloyed Titanium	Unalloyed Titanium	Same
Patient-contact material	Unalloyed Titanium Liquid crystal polymer Poly (etherimide) Stainless Steel	Unalloyed Titanium Polycarbonate Stainless Steel	Different
Sterilization	EO sterilized	Irradiation Sterilization	Different
Endotoxin Limit	20 EU	20 EU	Same
Biocompatibility			
Cytotoxicity Test	No cytotoxicity	Comply with ISO 10993	Same
Sensitization Test	No sensitization		

Instracutaneous Test	No irritation		
System Toxicity Test	No systemic toxicity		
Pyrogen Test	No pyrogen		

Different- Patient-contact material

The patient-contact material of the proposed device is different from the predicate device. However, the biocompatibility test has been conducted on the proposed device and the test result showed that the material of the proposed device does not have any adverse effect.

Different- Sterilization

The sterilization method of the proposed device is different from the predicate device. However, the sterilization process has been validated per ISO 11135 and the validation result showed that the sterilization method is effective.

Table 3 Technological Characteristics Comparison of Disposable Endoscopic Cutting Staplers

ITEM	Proposed Device	Predicate Device 2 K142577	Remark
Product Code	GDW	GDW	Same
Regulation No.	878.4750	878.4750	Same
Class	II	II	Same
Indication for Use	Disposable Endoscopic Cutting Staplers 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.	Similar
Main Configuration	Staple Knife Stapler	Staple Knife Stapler	Same
Operate Principle	Manual	Manual	Same
Cutting Mechanism	Linear Knife	Linear Knife	Same
Safety Mechanism	Safety release for preventing from	Safety release for preventing from	Same

	mis-firing	mis-firing	
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Specification	30mm, 45mm and 60mm	30mm, 45mm and 60mm	Same
Staple Height (mm)	2.5 mm, 3.5 mm, 4.0 mm or 4.8mm	2.0 mm, 2.5 mm, 3.5 mm, 4.0 mm or 4.8mm	Similar
Row number of Staple	6	6	Same
Closed Staple form	B-shape	B-shape	Same
Staple material	Unalloyed titanium	Unalloyed titanium	Same
Patient-contact material	Unalloyed Titanium Polyamide (nylon) Stainless Steel	Unalloyed titanium Stainless steel Polymeric materials Surgical grade stainless steels Adhesives and lubricants	Different
Sterilization	EO sterilized	EO sterilized	Same
Endotoxin Limit	20 EU	20 EU	Same
Biocompatibility			
Cytotoxicity Test	No cytotoxicity	Comply with ISO 10993	Same
Sensitization Test	No sensitization		
Instracutaneous Test	No irritation		
System Toxicity Test	No systemic toxicity		
Pyrogen Test	No pyrogen		

Similar-Indication for Use

The proposed device is not indicated for transection and resection of solid organ. However, the indication for use for the proposed device can be covered by the predicate device. Therefore, this difference will not raise any safety issues.

Similar- Staple Height

The proposed device staple height is not exactly same as the predicate device. However, the staple height of the proposed device can be covered by the predicate device. Therefore, the difference will not raise any safety issues.

Different- Patient-contact material

The patient-contact material is different from the predicate device. However, the biocompatibility test has been conducted on the proposed device and the test result showed that the material of the proposed device does not have any adverse effect.

8. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-1:2018 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization
- USP <85> Bacterial Endotoxins Test
- USP <151> Pyrogen Test
- ASTM F88/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 Package by Dye Penetration
- ISO 10993-11:2017 Biological Evaluation of Medical Device- Part 11: Tests for Systemic Toxicity
- ASTM D 4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F 756-17 Standard Practice for Assessment of Hemolytic Properties of Materials

The biocompatibility tests conducted on the proposed device include cytotoxicity test, skin sensitization test, intracutaneous irritation test, acute systemic toxicity test, pyrogen test and hemolysis test.

The material of implanted staple for the proposed devices is identical to that of the reference device, Disposable Powered Endoscopic Linear Cutting Staplers and Cartridges, as cleared in K202709 at 05/18/2021, which is also manufactured by the sponsor. The biocompatibility safety of the proposed device was addressed by leveraging the biocompatibility data of reference device and no additional biocompatibility tests were not tested on the staple.

A simulation transportation test was conducted on the proposed device per ASTM D 4169 and package integrity test include dye penetration and sealing strength test were followed to demonstrate that the package materials can maintain the package integrity without compromising the product sterility.

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

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are as safe, as effective, and perform as well as or better than the legally marketed predicate devices.