May 18, 2021

Ningbo Verykind Medical Device Co., Ltd.
% James Tsai
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K202709
Trade/Device Name: Disposable Powered Endoscopic Linear Cutting Staplers and Cartridges
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: August 30, 2020
Received: September 16, 2020

Dear James Tsai:

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,

Cindy Chowdhury, Ph.D., M.B.A.
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)*
K202709

Device Name
Disposable powered endoscopic linear cutting staplers and cartridges

Indications for Use *(Describe)*
Disposable Powered Endoscopic Linear Cutting Staplers and cartridges are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, abdominal, thoracic, and pediatric surgical procedures

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

K202709

1. Administrative Information

Date of Summary prepared	April 9, 2021
Manufacturer information	Company: Ningbo Verykind Medical Device Co., Ltd. Company address: #100 Jinghua Road, Hi-tech industrial development zone, Ningbo, Zhejiang 315040, China Contact person: Hong Pengfei Phone: +86-574-87910279 Fax: +86-574-87910279 E-mail: pfhong@nbverykind.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen Contact person: James Tsai E-Mail: james_tsai@cefda.com; field@cefda.com
Establishment registration number	

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Disposable Powered Endoscopic Linear Cutting Staplers and Cartridges
Classification name:	Implantable Staple
Review Panel:	General and plastic surgery devices
Product Code:	GDW
Device Class:	II
Regulation Number:	878.4750

3. Predicate Device Information

Manufacturer:	Ethicon Endo-Surgery, LLC
Trade Device:	Echelon Flex Powered Articulating Endoscopic Linear Cutters

510(K) Number:	K130653
Classification name:	Staple, Implantable; Stapler, Surgical
Product Code:	GDW
Device Class:	II
Regulation Number:	878.4750

4. Device Descriptions

The Disposable Powered Endoscopic Linear Cutting Staplers and Cartridges are sterile, single patient use instruments that simultaneously cut and staple tissue through a battery powered firing system. The instruments are packaged with a primary lithium battery pack which must be installed prior to use. The powered stapler and cartridges are sterilized by EO sterilization, and battery pack is sterilized by Gamma irradiation. The instruments deliver six staggered rows of staples, three on either side of the cut line.

The staplers are available in three shaft lengths: compact (Model DCE46 and DCE46, 280±10mm), regular (Model DSE46 and DSE60, 340±10mm) and long (Model DLE46 and DLE60, 440±10mm). The shaft can rotate freely in both directions and incorporates an articulation mechanism, which enables the distal portion of the shaft to pivot to facilitate lateral access to the operative site.

According to the length of the anastomosis, the cartridges (DCR series) can be divided into two specifications of 46mm and 60mm; the staples inside the cartridges can be divided into 2.5mm, 3.5mm, 3.8mm, 4.1mm according to the nail height, and they are distinguished by color. The color codes are white (W), blue (B), yellow (Y), and green (G). There are total 8 models of cartridges within the proposed device: two stapler line length: 46mm and 60mm, each length of the cartridges has four colors which stand for different staple heights: Green (4.1mm), Yellow (3.8mm), Blue (3.5mm), White (2.5mm).

The Disposable Powered Endoscopic Linear Cutting Staplers and Cartridges are powered by the internal lithium battery, which has the rated specifications of DC voltage 12V and capability 1400mAh. Battery package model is BP813, composed of four lithium battery cells. The proposed device is resistant to water ingress. Grade of waterproof：Rotating knob to the end of tubular shaft (including rotating knob) is rated IPX4; the Body is rated IPX0.

5. Intended Use/ Indications for Use

Disposable Powered Endoscopic Linear Cutting Staplers and cartridges are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, abdominal, thoracic, and pediatric surgical procedures.

6. Comparison to predicate device

Item		Disposable Powered Endoscopic Linear Cutting Staplers and Cartridges (Proposed device)	Echelon Flex Powered Articulating Endoscopic Linear Cutters (Predicate device, K130653)
Manufacturer		Ningbo Verykind Medical Device Co., Ltd.	Ethicon Endo-Surgery, LLC
Product Code		GDW	GDW
Classification		Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)
Intended use/ Indications for Use		Disposable Powered Endoscopic Linear Cutting Staplers and cartridges are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, abdominal, thoracic, and pediatric surgical procedures.	The Echelon families of endoscopic linear cutters (articulating and straight) are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.
Safety feature		Power stapler has empty-reload safety protection mechanism	Power stapler has empty-reload safety protection mechanism
Cutting mechanism		Stapler places two, triple staggered rows of staples and simultaneously cuts and divides the tissue between the two rows	Stapler places two, triple staggered rows of staples and simultaneously cuts and divides the tissue between the two rows
Cutting mechanism		Linear	Linear
Stapling power		Powered (Lithium Battery)	Powered
Suture Length		46mm, 60mm	45mm, 60mm
Staple height	Open	2.5mm, 3.5mm, 3.8mm, 4.1mm	2.0mm, 2.5mm, 3.5mm, 3.8mm, 4.1mm, 4.4mm
	Closed	1.0mm, 1.5mm, 1.8mm, 2.0mm	0.75mm, 1.0mm, 1.5mm, 1.8mm, 2.0mm, 2.3mm
Closed staple form			
Number of staples		70, 88	70, 88
Articulation angle		15°-60°	15°-45°
Rows of Staple Line		Six staggered rows of staples, three on either side of the cut line	Six staggered rows of staples, three on either side of the cut line
Implantable Material		Unalloyed Titanium conforms to ASTM F67-13	Unalloyed Titanium conforms to ASTM F67-13
Structures (main		It consists of Shell, Adjusting knob, Adjusting shell, Knife reverse button,	It consists of Shell, Adjusting knob, Adjusting shell, Knife reverse button,

components)	Firing safety, Battery pack, Manual override, Firing trigger, Close handle, Shaft, Anvil jaw, Reload jaw, Articulation protective sleeve, Cutting knife, Staple, Staple holder, Stapler holder cover		Firing safety, Battery pack, Manual override, Firing trigger, Close handle, Shaft, Anvil jaw, Reload jaw, Articulation protective sleeve, Cutting knife, Staple, Staple holder, Stapler holder cover
Body material patient short-time contact	Reload jaw: 06Cr19Ni10(SUS304), 05Cr17Ni4Cu4Nb(SUS630)		Not publicly available
	Anvil jaw: 06Cr19Ni10(SUS304), 05Cr17Ni4Cu4Nb(SUS630)		Not publicly available
	Articulation protective sleeve: TPU		Not publicly available
	Shaft: 06Cr19Ni10(SUS304)		Not publicly available
	Cutting Knife: 20Cr13 (SUS420J1), 30Cr13 (SUS420J2)		Not publicly available
	Staple: Ti (TA1G)		Not publicly available
	Stapler holder & cover: PC, ABS(PA757), PEI		Not publicly available
Biocompatibility	All components of the proposed device are composed of materials, which are in accordance with relevant parts of ISO Standard 10993		Conform to relevant parts of ISO standard 10993
Sterilization Sterility Assurance Level	Stapler and cartridges	Ethylene Oxide (EO) sterilization SAL 10^{-6}	Gamma Irradiation SAL 10^{-6}
	Battery	Gamma Irradiation SAL 10^{-6}	
Labeling	Conforms to 21 CFR part 801 and 830		Conforms to 21 CFR part 801 and 830

The proposed device and the predicate device have the same indications for use and similar technological characteristics. The differences in the materials, articulation angle and sterilization method do not raise additional questions for safety and effectiveness based on series tests, trials and validations.

7. Brief discussions of the nonclinical tests

All nonclinical tests performed on new devices are to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards.

Biocompatibility testing

The biocompatibility evaluations of the proposed device were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process”, as recognized by FDA. The biocompatibility testing includes the following:

- Cytotoxicity
- Sensitization & irritation
- Acute systemic toxicity
- Pyrogen test

The staplers are considered tissue contacting for duration less than 24 hours, while the staples are considered permanent implants. The titanium material of implantable staples conforms to ASTM F67-13.

Sterilization validation

Ethylene oxide and Gamma Irradiation are used to sterilize the proposed device, and the standards below are followed:

- 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
- ISO 11137-1:2006 Sterilization of health care products – Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2013 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ASTM F88:2015 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929:2015 Standard test method for detecting seal leaks in porous medical packaging by dye penetration
- Endotoxin Test

Performance testing

The following nonclinical tests were conducted with Disposable Powered Endoscopic Linear Cutting Staplers and Cartridges to verify that the proposed device is as safe and as effective as the predicate device, performs as intended, and meets all design specifications:

- Form staple height
- Stable line integrity
- Reliability testing
- Angle of articulation testing for the articulation connector change
- Safety system tests
- Reliability test for knife reverse button
- Appearance, Dimension and Surface roughness

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, and the results show that the proposed device complies with the following standards:

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) Medical electrical equipment - Part 1: General requirements for basic safety

and essential performance for safety

- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests standard for EMC
- IEC 60086-4:2014 Primary batteries - Part 4: Safety of lithium batteries

Animal study

To demonstrate the operation performance is as safe and as effective as the predicate device, the animal study was carried out to assess the following safety and performance criteria:

- Success rate of anastomosis
- Hemostasis evaluation test
- Anastomotic pressure resistance
- Anastomotic healing
- Staple forming
- Tensile strength & Burst pressure

MR Compatibility Information

Non-clinical testing demonstrated the staples in the device are MR conditional.

Summary

All the testing results, including bench tests, sterilization validation, biocompatibility tests and animal study, demonstrate that the Disposable powered endoscopic linear cutting staplers and cartridges manufactured by Verykind Company meet the requirements of its pre-defined acceptance criteria and intended use, and it has a safety and effectiveness profile that is similar to the predicate device.

8. Clinical Testing

Substantial equivalence does not depend on clinical test data.

9. Conclusions

Based on device comparison information and performance data, the proposed device is as safety and effectiveness as predicate device, and the differences in technological characteristics do not raise different questions of safety and effectiveness. Therefore, the proposed device is substantially equivalent to the predicate device.