January19, 2023

Changzhou Waston Medical Appliance Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K211197
Trade/Device Name: Disposable Endoscopic Cutter Stapler and Cartridge
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: January 6, 2023
Received: January 6, 2023

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 -S

Digitally signed by Mark Trumbore -S
Date: 2023.01.19 09:24:35 -05'00'

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)*
K211197

Device Name
Disposable Endoscopic Cutter Stapler and Cartridge

Indications for Use *(Describe)*
The Disposable Endoscopic Cutter Stapler and Cartridge has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis.The Disposable Endoscopic Cutter Stapler and Cartridge is not to be used in the transection and resection of solid organs.

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.

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: K211197

1. Date of Preparation: 01/19/2023

2. Sponsor Identification

Changzhou Waston Medical Appliance Co., Ltd
9 Xihu Road, Wujin Hi-Tech Industry Zone, Jiangsu Province, China

Establishment Registration Number: 3006717850

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Christina Wu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Disposable Endoscopic Cutter Stapler and Cartridge

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: I
Product Code: GAG;
Regulation Number: 21 CFR 878.4800
Review Panel: General & Plastic Surgery

Indications for Use:

The Disposable Endoscopic Cutter Stapler and Cartridge has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. The Disposable Endoscopic Cutter Stapler and Cartridge is not to be used in the transection and resection of solid organs.

Device Description:

Disposable Endoscopic Cutter Stapler and Cartridge 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 with cartridge in 2.0/2.5/3.0, 3.0/3.5/4.0, 4.0/4.5/5.0 three progressive staple sizes to accommodate carious tissue thickness. The device may be reloaded and fired up to 12 times in a single procedure.

5. Identification of Predicate Device

Predicate Device
510(k) Number: K161757
Product Name: 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 10993-1:2018 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-Part10: Test for irritation and delayed-type hypersensitivity.
- ISO 10993-11:2017 Biological evaluation of medical Devices-Part 11: Tests for systemic toxicity
- 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 <85> Bacterial Endotoxins Tests
- USP 43-NF 38 <151> Pyrogen
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.
- ASTM F 88/F88M-15 Standard test method for seal strength of flexible barrier materials;

Bench test was conducted on porcine stomach and intestine tissue for both proposed device and predicate device to determine substantially equivalence. The bench tests include following tests:

- Pressure Resistance Test
- Closed Staple Height Test
- Staple Formation Test
- Force Required to Fire Stapler Test

Biocompatibility test was conducted on the proposed device, the test includes cytotoxicity, irritation, skin sensitization, acute toxicity test and pyrogenicity.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison for the Disposable Endoscopic Cutter Stapler and Cartridge

Item	Proposed Device	Predicate Device K161757	Remark
Product Code	GDW	GDW	SE
Regulation No.	21 CFR 878.4750	21 CFR 878.4750	SE
Class	II	II	SE
Indication for Use	The Disposable Endoscopic Cutter Stapler and Cartridge has applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. The Disposable Endoscopic Cutter Stapler and Cartridge is not to be used in the transection and resection of solid organs.	The Single Use Endoscopic Linear Cutters and Reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.	SE Analysis 1
Configuration	Pin Shaft Articulation Lever Rotation Collar Green Firing Button Black Return Knob Light Blue Unload Button Loop Handle Anvil Lower Clamp Cover Staple Cartridge	Instrument Shaft Rotation Collar Rotation Knob Shell Black Return Knob Insurance Green Button Free Handle Staple Cartridge Anvil Cutting Knife Reload Shell	SE Analysis 2
Operation Principle	Manual	Manual	SE
Cutting Mechanism	Linear Knife	Linear Knife	SE
Safety Mechanism	Green button for preventing from mis-firing	Green button for preventing from mis-firing	SE
Suture Length	30mm,45mm,60mm	30mm,45mm,60mm	SE
Staple Height	2.0~3.0mm, 3.0~4.0mm, 4.0~5.0mm	2.0~3.0mm, 3.0~4.0mm, 4.0~5.0mm	SE

Closed staple height	0.88~1.22mm, 1.54~2.14mm, 1.92~2.28mm	0.8-1.5mm, 1.5-2.25mm, 2.25-3.0mm	SE Analysis 3
Row Number of Staples	6	6	SE
Staple Counts for Each Row	8, 11,15	7, 11,15	SE Analysis 4
Closed staple form			SE
Patient-contact material	Unalloyed Titanium Stainless Steel Polyamide	Unalloyed Titanium Acrylonitrile-Butadiene-Styrene Stainless Steel	SE Analysis 5
Sterilization	EO Sterilization	Irradiation Sterilization	SE Analysis 6
Endotoxin Limit	20EU	20EU	SE
Labeling	Conforms with 21CFR 801	Conforms with 21CFR 801	SE

SE Analysis 1 Indication for Use

The indication for use of proposed device is different from predicate device. The proposed device does not have the additional indication of transection and resection of liver substance, hepatic vasculature, biliary structures, and pancreas. However, the indication for use of proposed device can be covered by the predicate device. Therefore, this difference is considered not to affect the substantially equivalency between the proposed and predicate devices concerning the safety and effectiveness.

SE Analysis 2 Configuration

The configuration for proposed device is different from predicate device. By the proposed device and predicate device's performance test reports (Firing Force, Closed Staple Height, Pressure Resistance, Staple Formation), it proves that this difference is considered not to affect the substantially equivalency between the proposed and predicate devices concerning the safety and effectiveness.

SE Analysis 3 Closed staple height

The closed staple height for proposed device is different from predicate device. By the proposed device and predicate device's performance test reports (Closed Staple Height), it proves that this difference is considered not to affect the substantially equivalency between the proposed and predicate devices concerning the safety and effectiveness.

SE Analysis 4 Staple Counts for Each Row

The staple counts for proposed device are different from predicate device. By the proposed device and

predicate device's performance test reports (Firing Force, Closed Staple Height, Pressure Resistance, Staple Formation), it proves that this difference is considered not to affect the substantially equivalency between the proposed and predicate devices concerning the safety and effectiveness.

SE Analysis 5 Patient-contact material

The patient-contact material of proposed device is different from predicate device. However, the biocompatibility tests were performed on proposed device and the test result can meet the requirements of ISO 10993 series standards. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

SE Analysis 6 Sterilization

The sterilization method for proposed device is different from predicate device. However, the sterilization parameter for proposed device was established per ISO ISO11135 to achieve the SAL of 10^{-6}. Therefore, this difference is considered not to affect the substantially equivalency between the proposed and predicate devices concerning the safety and effectiveness.

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.