June 6, 2022

Beijing ZKSK Technology Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM. 1801, No.161, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
CHINA

Re: K213223
Trade/Device Name: Multi-Band Ligator
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: FHN, MND
Dated: September 20, 2021
Received: September 29, 2021

Dear Boyle Wang:

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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K213223

Device Name
Multi-Band Ligator

Indications for Use *(Describe)*
Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.

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

K213223

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

1.0 Submitter's Information

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Email: Info@truthful.com.cn

Date of Preparation: Apr.26, 2022

2.0 Device Information

Trade name: Multi-Band Ligator
Common name: Band Ligator
Classification name: Hemorrhoidal ligator.

Production code: FHN, MND
Regulation number: 21 CFR 876.4400
Classification: Class II
Panel: Gastroenterology/Urology

3.0 Predicate Device Information

Manufacturer: WILSON-COOK MEDICAL, INC.
Trade/Device Name: WILSON-COOK 10 SHOT MULTI-BAND LIGATOR 510(k) number: K974018

4.0 Device Description

Multi-band ligator inculding control handle (rotation handle, shaft and joint), loading catheter, irrigation adapter (irrigation pipe and base), barrel, trigger cord (cord and pellets) and loop.The barrel preloaded with 4~9 loops. This device is designed for attachment to the end of an endoscope for ligating esophageal varices or hemorrhoids. Once assembled and attached the endoscope is advanced to the desired banding site and individual bands are deployed via manipulation of the deployment handle and trigger cord. The multi-band feature allows for serial ligations, which reduces the need to remove the endoscope for reloading. This device is supplied non-sterile and is intended for single use only.

Models difference of the subject device depends on loops number and components, see Table 1.

Table 1 Multi-Band Ligator Models

Models	Loop No.	Components
BL18-4A	4 bands	Control handle (rotation handle, shaft and joint), loading catheter, irragation adapter (irrigation pipe and base), barrel, trigger cord（cord and pellets), loop.
BL18-5A	5 bands	
BL18-6A	6 bands	
BL18-7A	7 bands	
BL18-8A	8 bands	
BL18-9A	9 bands	
BL18-4M	4 bands	Loading catheter, irrigation adapter (irrigation pipe and base), barrel, trigger cord (cord and pellets), loop.
BL18-5M	5 bands	
BL18-6M	6 bands	
BL18-7M	7 bands	
BL18-8M	8 bands	
BL18-9M	9 bands	

5.0 Indication for Use Statement

Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.

6.0 Summary of Non-Clinical Testing

Summary of non-clinical and performance testing- Bench testing was performed to evaluate the performance and functionality of the subject device against requirement specification. The subject device has been subjected to compliance testing according

to Technical Requirements of Multi-Band Ligator. Results from testing performed confirms that the design requirement specification and user needs have been met. The subject device is confirmed to be safe and effective for the intended use.

7.1 Shelf life of Multi-Band Ligator is have successfully been tested according to ASTM F 1980-16. The label shelf life is 2 years.
7.2 Biocompatibility testing of Multi-Band Ligator has successfully been tested for cytotoxicity, sensitization and intracutaneously irritation. The test results verify that the biocompatibility criteria given in ISO 10993 are fulfilled. Multi-Band Ligator is biocompatible.
7.3 Performance testing – Bench: The performance of Multi-Band Ligator have been verified. Tests as described in table 1 have been completed.

Table 1: Performance testing summary – Bench

Test Item	Description
Appearance	To confirm that subject device is integrity and cleanliness and hygiene.
Functional performance	To confirm that the functions of the subject device complied with the Indication for Use.
Chemical properties	To confirm that pH, Total content of heavy metals, Potassium permanganate reductive substance, Evaporative residues and Ultraviolet Absorbance meet the related requirements.
Mechanical performance of the Loop	To confirm Hardness, Tensile strength, Tensile elongation and Tensile deformation meet the company's technical requirements.
Tensile strength	To conform the Tensile strength of the Trigger cord.
Physical properties of Irrigation adapter	To conform connection firmness, Inner surface and Luer connector
Leakage of the barrel	To check the tightness of the barrel, it shall have no leakage

7.0 Summary of Clinical Testing

No clinical study is included in this submission.

8.0 Technological Characteristic Comparison Table

Table 2- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device
510(k) No.	K213223	K974018
Product Code	FHN, MND	FHN, MND
Regulation No.	21 CFR 876.4400	21 CFR 876.4400

Class	II	II
Indication for Use	Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.	Used to endoscopically ligate esophageal varices at or above the gastroesophageal junction or to ligate internal hemorrhoids.
Components	1) Non-patient Contacting Loading Catheter; 2) Irrigation Adapter; 3) Barrel with preloaded loops 4) Trigger Cord 5) Multi-Band Ligator handle	1) Non-patient Contacting Loading Catheter; 2) Irrigation Adapter; 3) Barrel with 10 Ligation Bands 4) Trigger Cord 5) Deployment Handle
Patient Contacting Materials	Irrigation Adapter: Polyurethane Barrel: Polycarbonate (PC), silicone rubber Trigger Cord: Polypropylen (PE) Loop: Natural rubber	Friction Fit Adapter:Polyurethane Barrel:Polycarbonate Trigger Cord: Vectran Bands: Latex Rubber
Method of Use	Friction Fit adapter and barrel with ligation loops mounted to the distal tip of the endoscope. Band release from the barrel accomplished by trigger cord and Multi-Band Ligator handle.	Friction Fit adapter and barrel with ligation bands mounted to the distal tip of the endoscope. Band release from the barrel accomplished by trigger cord and deployment handle.
Loops(Bands)	Multiple loops (4~9)can perform serial ligations without removal of the endoscope for reloading of bands	Multiple bands (10)can perform serial ligations without removal of the endoscope for reloading of bands
Sterile	Non-sterile	Non-sterile
Shelf Life	2 years	3 years
Single Use	Single Use	Single Use
Performance Comparison testing	The test was conducted to the predicate device and current device to compare their functional performance.	
Biocompatibility	Conform with ISO10993-1 (ISO10993-5, ISO10993-10,)	Conform with ISO 10993 standards

The technological characteristics of the subject device are identical to those of predicate device. The subject device has the same basic design as the predicate device. The comparison between the subject and predicate devices is based on the following:

- Same intended use
- Same indications for use
- Similar material types that meet ISO 10993 biocompatibility requirements

• Same fundamental technology/principal of operation/user interface
The quantity of the loop of the subject device is 4,5,6,7,8,9 pcs, which is different with those of predicate device which is 10 pcs. But this difference will not raise any risk in safety and effectiveness.
Performance comparison testing was conducted to the predicate device and current device to compare their physical performance.It can be found the subject device incorporates substantially equivalent device materials, design, configuration, fundamental technology, sterilization process and intended use as those featured in the predicate device.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device in K974018 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.