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: K213222
Trade/Device Name: Disposable Polypectomy Snare
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: FDI
Dated: April 22, 2022
Received: May 2, 2022

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)*
K213222

Device Name
Disposable Polypectomy Snare

Indications for Use *(Describe)*
The Disposable Polypectomy Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.

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.

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510(k) Summary

K213222

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 Submitted: May.18, 2022

2.0 Device Information

Trade name: Disposable Polypectomy Snare
Common name: Polypectomy Snare
Classification name: Endoscopic electrosurgical unit and accessories

3.0 Classification

Production code: FDI
Regulation number: 21 CFR 876.4300
Classification: Class II
Panel: Gastroenterology/Urology

4.0 Predicate Device Information

Manufacturer: Zhejiang Chuangxiang Medical Technology Co., LTD.
Trade/Device Name: Disposable Polypectomy Snare
510(k) number: K172758

5.0 Device Description

The Disposable Polypectomy Snare consists of an insertion part and a handle part. The insertion part includes cutting loop(a flexible wire cable), traction wire, and sheath; the handle part includes sheath sleeve, locking sleeve, rotating sleeve, electrode connector, slider and a handle. The cutting loop can be extended and retracted from the Snare's flexible outer sheath using a three ring handle. The cutting loop can also be rotated 360° using the rotating actuator on the handle. The inner diameter of the sheath is PTFE to provide minimal friction during extension, rotation, and retraction of the loop from the sheath. When passed through an endoscope and activated, the Snare delivers a monopolar electrical current to cut and cauterize tissue with the loop.

The Disposable Polypectomy Snare is sterile for single use with no delayed hypersensitivity and no intracutaneous reactivity, have no animal or human origin substance.

The cutting loop of disposable polypectomy snare has four shapes to be used in clinical practice:
Ellipse type (E type), Hexagonal type (H type), Crescent type (C type), Round type (R type), and the loop can extend, retract from the snare's flexible outer sheath.

The materials used for construction of Disposable Polypectomy Snare are typical for this type of medical device. Materials of Cutting Loop is stainless steel 06Cr19Ni10, the Sheath is made of PTEF, the Electrode Connector is made of stainless steel SUS304. The Handle, Slider, Rotating Sleeve and Locking Sleeve are made of ABS, the Sheath Sleeve is made of HDPE.

6.0 Indication for Use Statement

The Disposable Polypectomy Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.

7.0 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, by FDA, recognized consensus standards ISO 10993-7, ISO 10993-1, ISO 11607-1, and Technical Requirements of "Disposable Polypectomy Snare" provided by

Beijing ZKSK Technology Co., Ltd. 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 Sterilization and shelf life of Disposable Polypectomy Snare is delivered sterile and have successfully been tested according to ISO 11607- 1. The label shelf life is 2 years.
7.2 Biocompatibility testing of Disposable Polypectomy Snare has successfully been tested for cytotoxicity, sensitization, intracutaneously irritation, acute systemic toxicity and material medicated pyrogenicity. The test results verify that the biocompatibility criteria given in ISO 10993 are fulfilled. Disposable Polypectomy Snare is non-toxic and biocompatible.
7.3 Performance testing – Bench: The performance of Disposable Polypectomy Snare has 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.
Dimension	To confirm that the dimensions of the subject device complied with the company's requirements.
Physical properties	To confirm the device functionality, tensile strength, cutting wire strength, electrical resistance tests and Compatible endoscopes tests.
Conduction resistance	The resistance between the connector and the Cutting Loop shall be $\leqslant$ 30Ω.
Corrosion resistance	should be no corrosive marks on the Cutting Loop.
Chemical properties	To confirm that pH, Total content of heavy metals, Potassium permanganate reductive substance, Evaporative residues and Ultraviolet Absorbance meet the related requirements.
Sterility	This device is sterilized by ethylene oxide. The device shall be sterile.
EO residue	EO residue shall be $\leqslant$10μg/g.

7.4 Electromagnetic Compatibility and Electrical Safety: Tests on Electromagnetic Compatibility and Electrical Safety were performed in accordance to requirements per IEC 60601-1:2005+A1:2012 ,IEC 60601-2-2:2017 and IEC 60601-1-2:2020.

8.0 Summary of Clinical Testing

No clinical study is included in this submission.

9.0 Technological Characteristic Comparison Table

Table 2- Comparison of Technology Characteristics

Item	Subject Device	Predicate Device
510(k) No.	K213222	K172758
Product Code	FDI	FDI
Regulation No.	21 CFR 876.4300	21 CFR 876.4300
Class	II	II
Intended Use	The Disposable Polypectomy Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.	The Polypectomy Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.
Configuration	Ellipse, Hexagonal, Crescent, Round	Oval, Hexagonal, Crescent, Round
Minimal working channel	2.8mm	2.8mm
Sheath OD.	2.4mm,1.8mm	2.4mm,1.8mm
Working Length	1600mm,1800mm,2400mm	1600mm,1800mm,2400mm
Loop width	10mm,15mm,22mm,25mm,32mm	10mm,15mm,22mm,25mm,32mm

Materials of Construction	Cutting Loop - Stainless Steel 06Cr19Ni10 (patient contacting) Sheath – Teflon (PTEF) (patient contacting) Traction Wire- Nitinol(non-patient contacting) Sheath Sleeve- HDPE(non-patient contacting) Locking Sleeve- Acrylonitrile / Butadiene / Styrene Copolymer (ABS)(non-patient contacting) Rotating Sleeve- Acrylonitrile / Butadiene / Styrene Copolymer (ABS)(non-patient contacting) Wire Pusher- Stainless Steel SUS304(non-patient contacting) Electrode Connector- H62(non-patient contacting) Slider- Acrylonitrile / Butadiene / Styrene Copolymer (ABS)(non-patient contacting) Handle- Acrylonitrile / Butadiene / Styrene Copolymer (ABS)(non-patient contacting)	Cutting loop made of stainless steel, Sheath made of Teflon (PTEF)
Target Population	Patients undergoing an endoscopic mucosal resection procedure	Patients undergoing an endoscopic mucosal resection procedure
Sterile	Ethylene Oxide, SAL: 10^{-6}	Ethylene Oxide, SAL: 10^{-6}
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 performance including device functionality, tensile strength, cutting wire strength, electrical resistance tests and Compatible endoscopes tests.	
Biocompatibility	Conform with ISO10993-1 (ISO10993-5, ISO10993-10, ISO10993-11)	Conform with ISO 10993 standards
Electromagnetic Compatibility and Electrical Safety	Conform with IEC 60601-1:2005+A1:2012,IEC 60601-2-2:2017and IEC 60601-1-2:2020	Conform with AAMI/ANSI ES 60601-1:2005/(R)2012 and AAMI/ANSI/IEC 60601-2-2:2009.

Compatible electrical surgical generators	ICC300 by ERBE Elektromedizin GmbH, Valleylab Force FX-8C by Medtronic, B.Braun Melsungen AG company produced GB300 high frequency electric burner device.	Not publicly available

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 sterilization methods
• Same fundamental technology/principal of operation/user interface

The type of the cutting loop of the subject device is same with those of predicate device, just the expression is in different words, ellipse or oval, the description of same shape.

The compatible electrical surgical generators of the predicate device are not publicly available. The function of the Cutting Loop of the proposed device and the predicate device remains the same in that it is attached to the generator to allow the flow of electrical energy to the cutting loop for the purpose of resecting tissue. The use of the different electrosurgical generator does not change the intended use or fundamental technology of the subject device.

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.

10.0 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 predicated device in K172758 and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.