September 22, 2022

Jiangsu Vedkang Medical Science and Technology Co.,Ltd.
℅ Joyce Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K220089
Trade/Device Name: Disposable Polyp Snare
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: FDI, FGX
Dated: August 18, 2022
Received: August 18, 2022

Dear Joyce Yang:

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)*
K220089

Device Name
Disposable Polyp Snare

Indications for Use *(Describe)*
The Disposable Polyp Snare is intended to be used in combination with endoscope for cutting polyps or other redundant tissues in digestive tract. The snare can be used with or without high-frequency current.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date of Summary prepare: December 30, 2021

1. Submission Sponsor

Applicant Name	Jiangsu Vedkang Medical Science & Technology Co., Ltd.
Address	No.52, Guoxiang Road, Wujin Economic Development Zone, Changzhou 213149, Jiangsu, P.R.China
Contact person	Tang Ting
Phone	+86 519 69877755

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen
Post Code	518000
Phone No.	+86-755-86069197
Contact Person	Joyce Yang
Email	joyce@cefda.com

3. Device Identification

Type of 510(k) submission:	Traditional
Trade Name:	Disposable Polyp Snare
Classification name:	Endoscopic Electrosurgical Unit and Accessories
Review Panel:	Gastroenterology/Urology
Product Code:	FDI FGX
Device Class:	2
Regulation Number:	21 CFR § 876.4300 21 CFR § 876.4730

4. Legally Marketed Predicate Device

Trade Name	Single Use Electrosurgical Snare SD-400
Regulation number	21 CFR § 876.4300

	21 CFR § 876.4730
Regulation class	2
Regulation name	Endoscopic electrosurgical unit and accessories
	Manual gastroenterology-urology surgical instrument and accessories
510(k) Number	K172734
Product Code	FDI
	FGX
Manufacturer	Aomori Olympus Co., Ltd.

5. **Device Description**

The subject device is intended to be used in combination with endoscope for cutting polyps or other redundant tissues in digestive tract.

The subject device consists of a handle section, a tube section and a loop section. The loop section is inserted into the tube section and is extended and retracted by operating the handle section.

The tube section and the loop section are inserted into the gastrointestinal tract through the endoscope. The loop is extended from the tube to resect the target tissue. The resection is performed with or without high-frequency current.

The shape of the loop includes oval, crescent, hexagonal, rhombus, dual-width oval, and polygonal. Users can choose the shape of the snare according to their preference and the characteristic of the lesion.

6. Intended Use/ Indications for Use

The Disposable Polyp Snare is intended to be used in combination with endoscope for cutting polyps or other redundant tissues in digestive tract. The snare can be used with or without high-frequency current.

7. **Technological characteristics comparison**

Comparison item	Subject Device: Disposable Polyp Snare (K220089)	Predicate Device: Single Use Electrosurgical Snare SD-400(K172734)	Comments
Product Code	FDI, FGX	FDI, FGX	Same
Regulation Number	21 CFR § 876.4300 21 CFR § 876.4730	21 CFR § 876.4300 21 CFR § 876.4730	Same
Classification	Class II	Class II	Same

Comparison item	Subject Device: Disposable Polyp Snare (K220089)	Predicate Device: Single Use Electrosurgical Snare SD-400(K172734)	Comments
Type of use	Prescription Use	Prescription Use	Same
Intended use & Indications for Use	The Disposable Polyp Snare is intended to be used in combination with endoscope for cutting polyps or other redundant tissues in digestive tract. The snare can be used with or without high-frequency current.	These instruments have been designed to be used with an Olympus endoscope for the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.	Same
Applicable user	The subject device is intended for use in people other than infants and young children.	The device is intended for use in people other than infants and young children.	Same
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital	Same
Single /repeat use	Single use	Single use	Same
Sterile /non-sterile	Marketed as a sterile device	Marketed as a sterile device	Same
Sterilization method and SAL	ETO sterile SAL=10^{-6}	ETO sterile SAL=10^{-6}	Same
Energy source	With or without High-frequency current	With or without High-frequency current	Same
Materials	Loop: stainless steel Tube sheath: Polytetrafluoroethylene (PTFE) Handle: ABS Protective sleeve: Polyurethane (PU)	Loop: stainless steel Tube: fluorocarbon polymer Handle: ABS	Similar
Patient - contact potential (Duration and type of contact)	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours)	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours)	Same
Configuration	Oval, Crescent, Hexagonal, Rhombus, Dual-width oval, Polygonal	Hexagonal	Different
Loop Width	6 mm, 10 mm, 15 mm, 20 mm, 25 mm, 30 mm, 35 mm, 40 mm, 45 mm, 50 mm	10 mm, 15 mm	Different
Working Length	1200 mm,1600 mm, 1800 mm, 2300 mm, 2400 mm, 3000 mm	2300 mm	Different

Comparison item	Subject Device: Disposable Polyp Snare (K220089)	Predicate Device: Single Use Electrosurgical Snare SD-400(K172734)	Comments
Tube sheath O.D.	1.8 mm, 2.3 mm	Unknown	Different
Minimal working channel	2.0 mm, 2.8 mm	2.8 mm	Different

8. Summary of non-clinical testing

Performance testing was conducted on the following items to support the marketing claims and to confirm that the safety and effectiveness of the Disposable Polyp Snare is at least equivalent to the predicate device.

- Size
- Strength
- Maneuverability
- Rotation degree of snare loop
- Cold cutting ability
- Hot cutting ability

The EO residual and ECH residual were measured after sterilization of the device to meet the criteria defined in ISO 11135 Second edition 2014 and ISO 10993-7:2008.

The shelf-life for three years had been validated in accelerated testing according to ASTM F1980-16 and the requirements on packaging for terminally sterilized medical device per ISO 11607-1:2006 are also met. The testing successfully demonstrated essential performance is achieved before and after the shelf life test.

The biocompatibility evaluations were conducted in accordance with the 2020 FDA Guidance document Use of International Standard ISO-10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The cytotoxicity, sensitization, intracutaneous irritation, system toxicity and pyrogen tests were performed to demonstrate the biocompatibility of the device.

Tests on Electromagnetic Compatibility and Electrical Safety were performed in accordance to requirements per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012

and IEC 60601-1-2 Edition 3: 2007-03, and in particular we also conducted tests on high frequency surgical equipment and accessories for endoscopes per IEC 60601-2-18:Edition 3.0 2009-08 and AAMI/ANSI/IEC 60601-2-2:2009.

9. Brief discussion of clinical tests

No clinical tests were performed.

10. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device, the Disposable Polyp Snares are as safe and effective, and performs as well as or better than the legally marketed predicate device cleared under K172734.