June 27, 2022

Yangzhou Fartley Medical Instrument Technology Co., Ltd.
% Ethan Liu, RA Specialist
Shanghai Thinkwell Consulting Co., Ltd
Room 211/6F, Xinling Road, Minhang District
Shanghai, Shanghai 201100
CHINA

Re: K220790
Trade/Device Name: Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: FDI
Dated: May 17, 2022
Received: May 23, 2022

Dear Ethan Liu:

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)*
K220790

Device Name
Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare

Indications for Use *(Describe)*
Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract. Disposable Polypectomy Snare shall be used with monopolar diathermic energy. Disposable Polypectomy Hybrid Snare shall be used with or without monopolar diathermic energy.

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

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

5.1 Submitter

Submitted by:	Yangzhou Fartley Medical Instrument Technology Co., Ltd. Address:Beizhou Road, Lidian Town, Guangling District, Yangzhou 225106 Jiangsu, China
Contact Person:	Ethan Liu RA Specialist Shanghai Thinkwell Consulting Co., Ltd Address: Room 211/6F, Xinling Road, Minhang Districtt, Shanghai, China. Phone: 0086-15216699240 Email: xtdeepwater@126.com
Date Prepared:	May 17, 2022

5.2 Device

Device Name:	Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare
Classification Name:	Endoscopic electrosurgical unit and accessories
Regulatory Class:	II
Regulation Number:	21 CFR 876.4300
Product Code:	FDI

5.3 Predicate Device

Device Name:	Polypectomy Snare K172729
Manufacturer:	Hangzhou AGS MedTech CO., Ltd.
Classification Name:	Endoscopic electrosurgical unit and accessories
Regulatory Class:	II
Regulation Number:	21 CFR 876.4300
Product Code:	FDI

5.4 Device Description

Disposable Polypectomy Snare

The Disposable Polypectomy Snare is available in two different types with rotating snare and non-rotating snare.

The cutting wire diameter of the snares is 0.4mm. The catheter diameters are 1.8mm and 2.4mm the depending on the version. The snares are available in different forms, lengths and openings depending on the type.

- Non-rotating snares

The non-rotating snare is available in six different loop shape: Oval, Hexagon, Lune, Combination, Multiple and Composite. The snares are available in the opening widths 10mm, 15mm, 20mm, 25mm,30mm, 35mm.The snares are available in the working lengths 1800mm and 2300mm.

- Rotatable snares

The rotary snare is available in six different loop shape: Oval, Hexagon, Lune, Combination, Multiple and Composite. The opening widths are 10mm, 15mm, 20mm,25mm, 30mm, 35mm, depending on the version. The snares are available in the working lengths 1800mm and 2300mm.

Disposable Polypectomy Hybrid Snare

The Disposable Polypectomy Hybrid Snare is available in two different types with rotating snare and non-rotating snare. Only one available loop shape is Hybrid.

The cutting wire diameter of the snares is 0.4mm. The catheter diameters is 2.4mm. The snares are available in different forms, lengths and openings depending on the type.

- Non-rotating snares

The non-rotating snare is available in the opening widths 10mm, 15mm,depending on the version.The snares are available in the working lengths 1800mm and 2300mm.

- Rotatable snares

The rotary snares are available 10mm, 15mm, depending on the version. The snares are available in the working lengths 1800mm and 2300mm.

5.5 Indication for Use:

Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract. Disposable Polypectomy Snare shall be used with monopolar diathermic energy. Disposable Polypectomy Hybrid Snare shall be used with or without monopolar diathermic energy.

5.6 Comparison of Technological Characteristics

The Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare has substantially equivalent device design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Hangzhou AGS MedTech CO., Ltd's Polypectomy Snare, K172729. The

differences between the proposed device and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below.

Item	Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare(Proposed Device)	Polypectomy Snare, K172729	Discussion
Indication for Use	Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract. Disposable Polypectomy Snare shall be used with monopolar diathermic energy. Disposable Polypectomy Hybrid Snare shall be used with or without monopolar diathermic energy.	Polypectomy Snare is used endoscopically in the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.	Substantially equivalent
Product Code	FDI	FDI	Same
Energy Use	Monopolar Radio Frequency Current	Monopolar Radio Frequency Current	Same
Loop Shape	**Disposable Polypectomy Snare:**Oval, Hexagon, Lune, Combination, Multiple and Composite **Disposable Polypectomy Hybrid Snare:**Hybrid	Hexagonal, Polygon , Oval, Round, Duck Bill	Substantially equivalent
Loop Width	**Disposable Polypectomy Snare:**10mm, 15mm, 20mm,25mm, 30mm, 35mm	Hexagonal: 10mm, 15mm, 25mm, 32mm Polygon:10mm, 15mm, 25mm, 32mm Oval:10mm, 15mm,	Similar

Item	Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare(Proposed Device)	Polypectomy Snare, K172729	Discussion
	Disposable Polypectomy Hybrid Snare:10mm, 15mm	25mm, 32mm Round: 10mm, 15mm, 25mm, 32mm Duck Bill: 10mm, 15mm, 25mm, 32mm	
Out tube diameter	**Disposable Polypectomy Snare:**1.8mm, 2.4mm **Disposable Polypectomy Hybrid Snare:**2.4mm	1.8mm, 2.4mm	Same
Working Length	1800mm, 2300mm	1800mm, 2300mm	Same
Sterilization	EO Sterilization; SAL:10^{-6}	EO Sterilization; SAL:10^{-6}	Same
Single Use	Yes	Yes	Same
Shelf Life	3 years	3 years	Same
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Same

5.7 Non-clinical Performance Data

The proposed device meets the requirements of ISO 10993 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing”, ISO 11135-1 “Sterilization of Health Care products Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”, and ISO 10993-7 “Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals” .

The following bench tests were performed on Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare: Appearance, Physical properties. The results of all testing were passing.

5.8 Clinical Test Data

No Clinical Study is included in this submission.

5.9 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Yangzhou Fartley

Medical Instrument Technology Co., Ltd. has demonstrated that proposed device Disposable Polypectomy Snare, Disposable Polypectomy Hybrid Snare is substantially equivalent to Hangzhou AGS MedTech CO., Ltd's currently marketed Polypectomy Snare, K172729.