May 28, 2026

Yangzhou Fartley Medical Instrument Technology Co., Ltd.
Xi Han
Quality Manager and Head of RA
Beizhou Road, Lidian Town, Guangling District
Yangzhou, Jiangsu 225106
China

Re: K260423
Trade/Device Name: Disposable Endoscopic Distal Attachments
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF, FDS
Dated: April 29, 2026
Received: April 29, 2026

Dear Xi Han:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SIVAKAMI VENKATACHALAM -S

for
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260423

Device Name
Disposable Endoscopic Distal Attachments

Indications for Use *(Describe)*
Disposable Endoscopic Distal Attachments are intended to be attached to the distal end of an endoscope to help maintain distance between the endoscope and tissue during endoscopic procedures.

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

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

1.1 Submitter

Submitted by:	Yangzhou Fartley Medical Instrument Technology Co., Ltd. Address: Beizhou Road, Lidian Town, Guangling District, Yangzhou 225106 Jiangsu, China
Contact Person:	Xi Han Quality Manager and Head of RA Phone: 0086-15051101225 Email: th@fartley.com
Date Prepared:	April 28, 2026

1.2 Device

Device Trade Name:	Disposable Endoscopic Distal Attachments
Common Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Product Codes: (primary listed first)	FDF, FDS
Classification Names:	Colonoscope And Accessories, Flexible/Rigid Gastroscope And Accessories, Flexible/Rigid
Regulatory Class:	II

1.3 Predicate Device

510(k) Number:	K202616
Device Trade Name:	ClearCap Distal Attachment
Manufacturer:	FINEMEDIX CO., LTD.
Common Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	OCX
Classification Name:	Endoscopic Irrigation/Suction System
Regulatory Class:	II

1.4 Device Description

Cone Straight

Disposable Endoscopic Distal Attachments are made of TPU, which is soft and flexible and can fit tightly to the distal end of the endoscope.

Disposable Endoscopic Distal Attachments are available in cone and straight shapes, with single-side hole and dual-side holes designs, respectively. Their outer diameter range from 10.9 mm to 16.4 mm, covering 10.9mm, 12.1mm, 12.3mm, 12.4mm, 13.2mm, 13.6mm, 14.0mm, 14.4mm, 15.2mm, and 16.4mm, and are compatible with various models of endoscopes.

1.5 Indications for Use:

Disposable Endoscopic Distal Attachments are intended to be attached to the distal end of an endoscope to help maintain distance between the endoscope and tissue during endoscopic procedures.

1.6 Comparison of Technological Characteristics

The proposed device Disposable Endoscopic Distal Attachments and the predicated device ClearCap Distal Attachment, K202616 has substantially equivalent device design, configuration, material, sterilization process and intended use. The size differences between the proposed device and the predicate devices do not raise any new questions regarding its safety and effectiveness. The differences are listed in the table below.

Item	Disposable Endoscopic Distal Attachments **(Proposed Device)**	ClearCap Distal Attachment, **K202616**	Discussion
Company	Yangzhou Fartley Medical Instrument Technology Co., Ltd.	FINEMEDIX CO., LTD.	/
Indications for Use	Disposable Endoscopic Distal Attachments are intended to be attached to the distal end of an endoscope to maintain distance between the endoscope and tissue during endoscopic procedures.	The ClearCap Distal Attachment has been designed to be attached to the distal end of the endoscope to facilitate endoscopic therapy. The ClearCap Distal Attachment is intended for the following: • Gastrointestinal mucosal resection (endoscopic mucosal resection) • Keeping the suitable depth of the endoscope's view field	Similar
Product Code	FDF, FDS	OCX	The difference in product codes does not raise new questions of safety or effectiveness.
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Classification	II	II	Same
Principle of Operation	Disposable Endoscopic Distal Attachments are intended to be attached to the distal end of an endoscope to maintain distance between the endoscope and tissue during endoscopic procedures and to ensure visibility by discharging bleeding and some foreign substances through one or more side holes.	It is attached to the end of the endoscope device to maintain proper distance from the tissue and to ensure visibility by discharging bleeding and some foreign substances through two holes on the side.	Difference in number of side holes does not raise new safety or effectiveness questions. Non-clinical testing used to support substantial equivalence.
Material	Thermoplastic Polyurethane (TPU)	Thermoplastic Polyurethane (TPU)	Substantial equivalence supported by non-clinical testing.

Biocompatibility	Acceptable, per ISO 10993-1	Acceptable, per ISO 10993-1	Substantial equivalence supported by biocompatibility testing and evaluation.
Outer Diameter	10.9mm, 12.1mm, 12.3mm, 12.4mm, 13.2mm, 13.6mm, 14.0mm, 14.4mm, 15.2mm, 16.4mm	11.35mm, 11.8mm, 12.4mm,13.4mm, 14.0mm, 15.0mm, 15.7mm	Substantial equivalence supported by non-clinical testing.
Inner Diameter	9.0mm 10.2mm 10.4mm 10.5mm 11.3mm 11.7mm 12.1mm 12.5mm 13.3mm 14.5mm	8.9mm 9.4mm 10mm 11mm 11.6mm 12.6mm 13.3mm	Substantial equivalence supported by non-clinical testing.
Maximum Diameter of Attaching Endoscope	8.9mm-15.0mm	9.4mm, 9.8mm, 10.5mm, 11.7mm, 12.2mm, 13.7mm, 13.9mm	Substantial equivalence supported by non-clinical testing.
Number Side Holes	1 hole and 2 holes	2 holes	Substantial equivalence supported by non-clinical testing.
Reuse or Single Use	Single use	Single use	Same
Sterile	EO Sterilization	EO Sterilization	Same
Environment of Use	Hospital/clinics	Hospital/clinics	Same

1.7 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 Endoscopic Distal Attachments: Appearance, Size, Hardness, Compatibility, Firmness, Field of View. The results of all testing were passing.

1.8 Clinical Test Data

No Clinical Study is included in this submission.

1.9 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 Endoscopic Distal Attachments is substantially equivalent to the predicated device of ClearCap Distal Attachment, K202616.