May 30, 2025

Alton (Shanghai) Medical Instruments Co. Ltd
Song Wei
Project Engineer
No.24 Building Jinshao Rd.1688.Baoshan District
Shanghai, Shanghai 200949
China

Re: K242635
Trade/Device Name: Endoscopic Distal Attachment (AF-D series)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, FDF
Dated: April 30, 2025
Received: April 30, 2025

Dear Song Wei:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Shanil P. Haugen -S

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)*
K242635

Device Name
Endoscopic Distal Attachment (AF-D series)

Indications for Use *(Describe)*
Endoscopic Distal Attachment is intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.

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

I. SUBMITTER

Name: Alton (Shanghai) Medical Instruments Co. Ltd.

Address: No.24 Building, JinShao Rd. 1688, Baoshan District, 200949 Shanghai, P. R. China

Name of contact person: Vivian Li

Position: Director of Quality Department

Tel: +86 21 56771811

Fax: +86 21 66307823

Mail: vivian@alton.com.cn

Date prepared: 2025-04-28

II. Identification of Subjective Device

Device trade name: Endoscopic Distal Attachment (AF-D series)

Regulation Name: Endoscope and accessories

Regulation number: 21 CFR 876.1500

Regulation class: 2

Review Panel: Gastroenterology/Urology

Product Code Descriptions: Gastroscope And Accessories, Flexible/Rigid;

Colonoscope And Accessories, Flexible/Rigid

Product code: FDS, FDF

III. Identification of Predicate device

Predicate Submission Number: K162749

Trade/Device Name: FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR

Regulation Name: Endoscope and accessories

Regulation Number: 21 CFR 876.1500

Regulatory Class: 2

Review Panel: Gastroenterology/Urology

Product Code Descriptions: Gastroscope And Accessories, Flexible/Rigid;

Colonoscope And Accessories, Flexible/Rigid

Product Code: FDS, FDF

IV. Device description

The Endoscopic Distal Attachment is an additional device, made of TPU designed to attach to the distal end of the endoscope. The device is composed of three main portions: an attaching portion, a distal portion, and a drain portion. The attaching portion is a wider diameter opening which is used to connect the attachment to a compatible endoscope; the distal portion is the ending portion of the attachment which tapers into narrower diameter opening. The hole, which is only available for some models, forms drain portion which prevent the fluids lodging on the surface of the endoscope.

The Endoscopic Distal Attachment can be used in combination with compatible endoscopes to maintain an appropriate endoscopic field of view.

The Endoscopic Distal Attachment has six models, depending on different surface design (flat or incline), with or without hole and with scale or without scale. The models include models of flat face without hole, flat face with hole, inclined face without hole, inclined face with hole, flat face without hole with scale and flat face.

V. Indication for use

Endoscopic Distal Attachment is intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.

Attribute	Subject device	Predicative device (K220884)	Discussion/ Conclusion
Manufacturer	Alton (Shanghai) Medical Instruments Co. Ltd	Fujifilm Medical Systems USA, Inc.	/
Trade name	Endoscopic Distal Attachment	FUJIFILM Hood	/
Regulation name	Endoscope and accessories	Endoscope and accessories	Same
Regulatory Class	II	II	Same
Product code	FDS, FDF	FDS, FDF	Same
Clinical characteristics			
Indications for use	Endoscopic Distal Attachment is intended to be used in combination with compatible endoscopes to maintain the field of' view during endoscopic procedures such as mucosal resection.	The FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR are intended to be used in combination with compatible endoscopes to maintain the field of view during endscopic procedures such as mucosal resection.	Same
Compatible endoscopes	Olympus® series: GIF-H190; GIF-Q260;	Fujifilm's endoscopes: EG-590WR, EG-580RD,	Different, see below

Attribute	Subject device	Predicative device (K220884)	Discussion/ Conclusion
	PCF-PQ260L; PCF-PQ260I; SIF-Q260; GIF-H260; GIF-H290Z; GIF-Q260J; CF-Q260DL; CF-Q260DI; CF-Q260AL; CF-Q260AI; CF-H290; CF-HQ290ZL/I; CF-HQ290L/I; CF-H290L/I; CF-HQ190L/I; CF-H190L/I; CF-HQ290ZL/I; CF-HQ290L/I; CF-HQ190L/I; CF-H190L/I; CF-FH260AZI Fujifilm®: EG-760R; EG-720R; EG-600WR; EG-L600WR7; EG-L580RD7; EG-L580RD; EG-580RD; EC-450RD5/M; EC580RD/M; EC-740T/M, L; EG-L600ZW; EG-600ZW; EG-760Z; EG-760CT; EG-590ZW; EG-590ZW2; EG-L590ZW; EI-740D/S; EC-760Z-V/M, L; EC-760S; EC-720R/M, I, L; EC-L590ZW; EC-590ZW3/M; EC-590ZW/M; EC-600ZW/M; EC-590WM Pentax®: EG27-i10; EG29-i10; EG29-i10N; EG29-i20c; EC34-i10M; EC34-i10L; EC34-i10F; EC38-i10L; EC38-i10F/F2; EC38-i10M/M2; EC38-i20c;	EC-580RD/M, EC-580RD/L, EG-600ZW, EG-530CT, EG-590ZW, EC-590WM, C-590ZW/M, EC-590ZW/L, EC-530WM3, EC-530WI3, EC-530WL3, EC-530DL, ES-530WE, EC-590WM4, EC-590WI4, EC-590WL4, EC-590ZW3/M, EC-590ZW3/L, EC-600WM, EC-600WI, EC-600WL, EC-600WL v2, EC-600HL, EC-600ZW/M, EC-600ZW/L	discussion
General technological characteristics			
Device composition and Principle of Operation	The Endoscopic Distal Attachment is an additional device, made of medical grade silicone rubber designed to attach to the distal end of the endoscope. The device is composed of three main portions: an attaching portion, a distal portion, and a drain portion. The attaching	The FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR are comprised of three main sections: an attaching portion, a distal portion, and a drain portion. The attaching portion is a wider diameter opening which is used to connect the hood to an applicable endoscope; a distal portion is the	Same

Attribute	Subject device	Predicative device (K220884)	Discussion/ Conclusion
	portion is a wider diameter opening which is used to connect the attachment to a compatible endoscope; the distal portion is the ending portion of the attachment which tapers into narrower diameter opening. The hole, which is only available for some models, forms drain portion which prevent the fluids lodging on the surface of the endoscope.	ending portion of the hood which tapers into narrower diameter opening, the drain slits on the distal portion form drain portion which prevent the fluids lodging on the surface of the endoscope.	
Outer diameter	11.7mm; 12.1mm; 12.2mm; 12.6mm; 12.9mm; 13.7mm; 14mm; 14.4mm; 14.8mm; 16.4mm	DH-28GR: 11.8mm; DH-29CR: 13.0mm; DH-30CR: 14.8mm	Different, see below discussion
Maximum diameter of attaching endoscope	13.7mm~18.4mm	DH-28GR: 15.5mm DH-29CR: 16.5mm DH-30CR: 18.4mm	Different, see below discussion
Total length	14mm	17.0mm	Different, see below discussion
Distance from the tip	4mm	7.0mm	Different, see below discussion
Diameter of attaching portion	9.2mm; 9.8mm; 9.9mm; 10.5mm; 10.8mm; 11.5mm; 11.8mm; 12.2mm; 12.8mm; 13.2mm; 14.8mm	DH-28GR: 10.4 - 11.3 mm; DH-29CR: 11.6 - 12.3 mm; DH-30CR: 13.4 - 14.2 mm	Different, see below discussion
Size and number the drain	Models without hole: No holes Models with hole: Circular hole, φ 3mm	Square hole, 5.0mm×1.25mm	Different, see below discussion
Sterilization	Ethylene Oxide sterilization	Ethylene Oxide sterilization	Same
Single use/reuse	For single use	For single use	Same
Shelf life	3 years	Not known	Different, see below discussion

Discussion on differences between the subject device and the predicate device The principle of operation and intended use of the subject device AF-D series are identical to that of the predicate device FUJIFILM Hood Model DH-28GR, DH-29CR, DH-30CR (K162749). The modifications done to the subject device include changes in dimensions to make it be applicable to different specifications of endoscopes from different manufacturers. Comparison of performance tests have been conducted on the subject device and the predicate device to validate the mechanical performance of the subject device is equivalent to the predicate device. In addition, tests to address safety against tissue damage, connection reliability and resistance against endoscope damage in combination assembly with the compatible endoscopes have been conducted on the subject device, the favorable test results demonstrated the subject device's safety on such issue concerns. Such differences do not alter the intended use or fundamental technology of the subject devices neither affects their safety and effectiveness.

VII. Summary of substantial equivalence discussion

Based on the above comparison table as well as discussion on differences, the subject device and the predicate device have similar design features and performance specifications. There are no differences on device composition and component material used on both devices. Although there are some differences on size specification parameters on the subject device and predicate device, such differences will not affect the effectiveness and safety of the subject device as different size design is dependent on the different size of the applicable endoscope. In addition, a performance comparison testing between the subject device and the predicate device is implemented and all performances including mechanical property and chemical property are verified to confirm the performance of the subject device is substantially equivalent to the predicate device. These technological differences between the subject device and the predicate device do not affect the safety and effectiveness of the subject device when used as labeled.

VIII. Summary of Non-clinical Data

Non-clinical testing for Endoscopic Distal Attachment was conducted to verify that the subject device met all design specifications, demonstrated safety and essential

performance based on current applicable standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed.

- Biocompatibility

The biocompatibility evaluation for the Endoscopic Distal Attachment was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

- MTT Cytotoxicity Test: ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- Skin Sensitization Test, Skin Irritation Test: ISO 10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization
- Acute Systemic Toxicity Test and Pyrogen Test: ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

- Sterilization Validation

  The EO sterilization of the Endoscopic Distal Attachment has been validated according to the following applicable standards:

  - ISO11135:2014+A1:2018 Sterilization of medical device- validation and routine control of ethylene oxide sterilization
  - ISO 11737-2:2019 Sterilization of Medical Device-Microbiological methods-part 2: Tests of sterility performed in the validation of a sterilization process
  - ISO 10993-7:2008+A1: 2019 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

- Shelf Life and Sterile Barrier System

  Shelf Life and Sterile Barrier System of the Endoscopic Distal Attachment has been validated according to the following applicable standards:

  - ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier

Systems for Medical Devices

- ISO11607-1:2019 Packaging for terminally sterilized Medical Device Part 1: Requirement for materials，sterile barrier systems and packaging systems
- ISO11607-2:2019 Packaging for terminally sterilized Medical Device Part 2: Validation Requirement for forming, sealing and assembly process
- ASTM F 1929-15: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM D 3078-02(2013): Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- DIN 58593-6: 2016 Sterilization – Sterile Supply – Part 6: Microbial Barrier Testing of Packaging Materials for Medical Devices Which Are to Be Sterilized
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D4169-22 Standard practice for performance testing of shipping containers and systems (DC-13, Level II)

➢ Performance Data – Bench

The performance tests were implemented on both the subject device and the predicate device to demonstrate substantial equivalence according to the product specification as below listed:

- Appearance
- Sizes
- Endoscope Compatibility
- Operational performance according to ISO 8600-1: 2015 and ISO 8600-4: 2023
- Safety against tissue damage
- Connection reliability and Resistance against endoscope damage in combination assembly with the compatible endoscope

➢ Performance Data – Animal

N/A, no animal studies are available for the subject device.

IX. Summary of Clinical Data

N/A, no clinical studies are available for the subject device.

X. Conclusions

In conclusion, the technological characteristics, features, specifications, materials, principle of operation, and intended use of the subject device substantially equivalent to the predicate devices quoted above. The differences between the subjective device and its predicate devices do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. From the results of nonclinical testing described, it can be concluded that the subject device is substantially equivalent to the legally marketed predicate device.