February 6, 2026

Fujifilm Corporation
% Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
Fujifilm Healthcare Americas Corporation
81 Hartwell Ave. Suite 100
Lexington, Massachusetts 02421

Re: K253568
Trade/Device Name: Hood DH-084STR; Hood DH-094STR; Hood DH-104STR; Hood DH-114STR; Hood DH-124STR; Hood DH-134STR
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, FDF
Dated: January 9, 2026
Received: January 9, 2026

Dear Chaitrali Kulkarni:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253568

Please provide the device trade name(s).

Hood DH-084STR;
Hood DH-094STR;
Hood DH-104STR;
Hood DH-114STR;
Hood DH-124STR;
Hood DH-134STR

Please provide your Indications for Use below.

These hoods are intended to be used in combination with the compatible endoscope to maintain the field of view during endoscopic procedures or examinations.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253568

510(k) Summary

Prepared on: 2026-01-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Fujifilm Corporation
Applicant Address	798 MIYANODAI KAISEI-MACHI ASHIGARAKAMI-GUN KANAGAWA 258-8538 Japan
Applicant Contact Telephone	704-517-4886
Applicant Contact	Ms. Chaitrali Kulkarni
Applicant Contact Email	hcusregulatoryaffairs@fujifilm.com
Correspondent Name	Fujifilm Healthcare Americas Corporation
Correspondent Address	81 Hartwell ave suite 100 Lexington MA 02421 United States
Correspondent Contact Telephone	704-517-4886
Correspondent Contact	Ms. Chaitrali Kulkarni
Correspondent Contact Email	hcusregulatoryaffairs@fujifilm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Hood DH-084STR; Hood DH-094STR; Hood DH-104STR; Hood DH-114STR; Hood DH-124STR; Hood DH-134STR
Common Name	Endoscope and accessories
Classification Name	Gastroscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FDS, FDF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193123	Hood DH-33GR; Hood DH-34CR; Hood DH-40GR; Hood DH-35GZ; Hood DH-37CZ; Hood DH-38CZ; Hood DH-39CZ	FDS

Device Description Summary

21 CFR 807.92(a)(4)

These hoods are intended to be used in combination with the compatible endoscope to maintain the field of view during endoscopic procedures or examinations.

This product is attached to the tip of our endoscope and is designed to prevent the mucosa from obstructing the surgical field of view during observation of the digestive tract or during endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD), thereby ensuring a clear field of view during the procedure.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

These hoods are intended to be used in combination with the compatible endoscope to maintain the field of view during endoscopic procedures or examinations.

Indications for Use Comparison 21 CFR 807.92(a)(5)

There is slight difference in the description of the predicate device compared to the proposed device. However, the difference does not raise any new concerns for safety or efficacy.

Technological Comparison 21 CFR 807.92(a)(6)

The differences in the sizes of the proposed hood model and the predicate hood model does not affect the safety or efficacy of the proposed model because we are conducting compatibility verification with endoscopes using the worst-case model specifications for combination endoscopes.

The proposed device and the predicate device have a difference in material. The material construction of the proposed devices has been evaluated through biocompatibility testing and no new concern for the safety and efficacy was seen.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The changes to the proposed device model are in the dimensions as outer diameter, maximum diameter of attaching endoscope, distance from the tip, total length and combination endoscope. To determine if the changes would affect the safety or efficacy of the subject device, performance testing was conducted, and the subject device passed all test objectives. It was determined that the new hood model is substantially equivalent to the predicate devices.

Endoscope specific testing was conducted according to ISO 8600-1: 2015

The proposed device met performance specifications in the following additional testing:

- Outer diameter: Measure the diameter of Maximum diameter portion by a scale.
- Maximum diameter of attaching endoscope: Measure the diameter of Maximum diameter portion by a scale.
- Total length: Measure the total length by a scale.
- Distance from the tip: Measure the distance from the tip by a scale.