March 9, 2026

FUJIFILM Corporation
% Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
FUJIFILM Healthcare Americas Corporation
81 Hartwell Ave
Suite 300
Lexington, Massachusetts 02421

Re: K251861
Trade/Device Name: FUJIFILM Endoscope Model ED-S100TP; FUJIFILM Endoscope Model ED-S100XP; FUJIFILM Processor Model VS-1000
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDT, FET
Dated: February 6, 2026
Received: February 6, 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 13485 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 Medical Device File (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

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.

Submission Number *(if known)*

K251861

Device Name

FUJIFILM Endoscope Model ED-S100TP;
FUJIFILM Endoscope Model ED-S100XP;
FUJIFILM Processor Model VS-1000

Indications for Use *(Describe)*

a) ED-S100TP, ED-S100XP
This product has been designed for endoscopy and endoscopic surgery within the duodenum.

b) VS-1000
This product is a non-sterile, reusable display device designed to display live image data from FUJIFILM single-use endoscope.

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.

510(k) #: K251861

510(k) Summary

Prepared on: 2026-02-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FUJIFILM Coporation
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Applicant Contact	Ms. Chaitrali Kulkarni
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Correspondent Contact	Ms. Chaitrali Kulkarni
Correspondent Contact Email	hcusregulatoryaffairs@fujifilm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	FUJIFILM Endoscope Model ED-S100TP; FUJIFILM Endoscope Model ED-S100XP; FUJIFILM Processor Model VS-1000
Common Name	Endoscope and accessories
Classification Name	Duodenoscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FDT, FET

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K980465	Olympus TJF-140R/JF-140R Duodenovideoscopes	FDT
K191747	FUJIFILM Duodenoscope Model ED-580XT	FDT
K233886	Ambu® aScope™ Duodeno 2	FDT
K072957	Olympus CV-180/CLV-180	NWB

Device Description Summary

21 CFR 807.92(a)(4)

A. Intended Use/indications for Use

a) ED-S100TP,ED-S100XP
This product has been designed for endoscopy and endoscopic surgery within the duodenum.

b) VS-1000
This product is a non-sterile, reusable display device designed to display live image data from FUJIFILM single-use endoscope. For information on indications for use, refer to the operation manuals of compatible FUJIFILM single-use endoscopes.

B. Technological characteristics
a) ED-S100TP,ED-S100XP
This product is a medical electronic side viewing endoscope for duodenum, and it is inserted into the lumen, coelom, body cavity, or inside of the body, which provides images for observation, diagnosis, photographing, or treatment. The device is used for observation, diagnosis and treatment of the duodenum, in medical institutions under the supervision of a physician. The device is equipped with a bending part which enables to move the distal end part in 4 different directions such as up and down, right and left. The device consists of a flexible tube with the bending part, and the operating part with the lever to operate the bending part. The tube inside of the flexible tube is installed from the operating part to the distal end part. Inserting treatment tools into the conduit line (referred as 'forceps channel') enables trans-endoscopic treatment.
This product is a sterile single-use device and is not intended for reprocessing.

b) VS-1000
This product has image processing, light source control, AE (shutter) control functions, a connector for endoscopes, and a connector for display units, and provides images for observation, diagnosis, photography, or treatment in body cavities by connecting the display unit and endoscope.

C. Principles of Operation
a) ED-S100TP,ED-S100XP
This product is lighted by LED at the tip. Its reflection forms an image on CMOS image sensor through a group of object lens placed and set in the tip of this product. An electric signal from CMOS image sensor is transmitted to the processor connected to this product. The processor converts it to a video signal and displays an image on a monitor.
Since there are no exposed metal parts (conductive parts) on the endoscope surface that can be contacted in use, the endoscope can safely perform procedures using high-frequency current.

b) VS-1000
The product controls the light source mounted on the endoscope, receives electrical signals output from the endoscope's image sensor and outputs them as video signals to the display unit after performing image processing such as colour and image quality correction and enhancement.
The display unit's operating console and the endoscope application software built into the display unit are used to manage patient information, adjust white balance, and provide images and patient information to network devices.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

a) ED-S100TP, ED-S100XP
This product has been designed for endoscopy and endoscopic surgery within the duodenum.

b) VS-1000
This product is a non-sterile, reusable display device designed to display live image data from FUJIFILM single-use endoscope.

Indications for Use Comparison

21 CFR 807.92(a)(5)

a) ED-S100TP, ED-S100XP
There is a difference between the predicate device and the proposed devices, but the IFU for the predicate device includes information that it is designed for endoscopic examination and endoscopic surgery of the duodenum, which is the intended use of the proposed devices.

b) VS-1000
The IFU descriptions for the proposed device and the predicate device differ, but both are intended to be used as a system to display live image data.

Technological Comparison

21 CFR 807.92(a)(6)

a) ED-S100TP, ED-S100XP

Proposed device models come with optical characteristics compared to predicate devices. The differences in the optical characteristics have been tested through Bench testing and no new concern for safety or efficacy was seen.
Proposed device model has differences in viewing direction, observation range with predicate device but it is same as reference models already on the market, there are no new concerns for safety or efficacy.
The difference in field of view does not affect the safety or efficacy of the proposed device because observation range of proposed device is wider than predicate device
Proposed device models have differences in LED method, but this method is same as reference model. The method of illumination is different, but the safety and efficacy were not affected by the light safety test.
Proposed device model has differences in distal end diameter, flexible portion diameter and maximum insertion diameter with predicate models, but proposed devices is smaller than the predicate devices. There are no safety issues.
As the difference of forceps channel diameter, working length and total length is same as reference models or between the specifications of several models already on the market, there are no new concerns for safety or efficacy.
The processors used are different, but we have conducted benchmark tests to confirm that there is no impact on the safety or effectiveness of the images.
The proposed device models have differences in materials in comparison to the predicate devices. The differences in the materials have been tested through biocompatibility testing and no new concern for safety or efficacy was seen.

b) VS-1000
The difference in the built in battery allows the device to be used while charging. No new concerns for safety or efficacy was seen.
The difference in the connectivity does not affect safety or effectiveness. Images are displayed on a display unit that is used in combination.
The difference in the connectivity does not affect the safety or efficacy of the proposed device. Images can be extracted to USB memory in the same way as for the predicate device.
The differences in the dimensions and weight do not affect the safety of efficacy of the proposed device. The subject device is more compact and lighter than the predicate device, no new concerns of safety or efficacy were seen.
As for the type of protection against electric shock, predicate device is class I but proposed device is class II. The proposed device is of a higher class and is therefore equivalent to or better than the predicate device.
Both provide recording and data storage and transport function.
Both share certain technical functionalities as auto white balance and zoom function.

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

The performance of Image and the performance of FUJIFILM Video Processor VS-1000 and Endoscope ED-S100XP was evaluated according to the engineering requirements listed in this section.

The Endoscope ED-S100TP and Endoscope ED-S100XP use the same optical system and sensor, so testing was performed on the ED-S100XP as representative.
The following test reports are provided:(1)Image Geometric Distortion, (2)Image Resolution Performance, (3)Depth of field (DOF) Performance Test, (4)ISO-SNR & Dynamic Range Performance,(5)Image intensity uniformity,(6)Color Performance

Although there are minor differences between the proposed and predicate devices, these differences do not raise new or additional questions of safety or effectiveness of the proposed devices. Thus, the proposed device VS-1000 and ED-S100XP is substantially equivalent to the predicate device.

The following performance for the Endoscope ED-S100TP and Endoscope ED-S100XP were evaluated according to the engineering requirements listed in this section. In all cases, the devices met the predefined acceptance criteria for the test.

(1)Bending Capability, (2)Working length (3)Diameter of forceps channel (4)Air volume (5)Water volume, (6)Rate of Suction (7) Field of view, (8)Viewing direction, (9)Resolution, (10)Visualization Brightness at Distances, (11)Color reproducibility (12)Guidewire Lock (13) ERCP evaluation (14) Elevator Angulation

Although there are minor differences between the proposed and predicate devices, these differences do not raise new or additional questions of safety or effectiveness of the proposed devices. Thus, the proposed device the Endoscope ED-S100TP and Endoscope ED-S100XP is substantially equivalent to the predicate device and reference devices.