February 17, 2026

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

Re: K250550
Trade/Device Name: FUJIFILM Endoscope Model EG-S100XT; FUJIFILM Processor Model VS-1000
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, FET
Dated: January 16, 2026
Received: January 16, 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,

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.

Submission Number *(if known)*

K250550

Device Name

FUJIFILM Endoscope Model EG-S100XT;
FUJIFILM Processor Model VS-1000

Indications for Use *(Describe)*

a) EG-S100XT
This product is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and 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) #: K250550

510(k) Summary

Prepared on: 2026-01-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FUJIFILM Coporation
Applicant Address	798 Miyanodai Kaisei-Machi Ashigarakami-Gun Kanagawa 258-8538 Japan
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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 EG-S100XT; FUJIFILM Processor Model VS-1000
Common Name	Endoscope and accessories
Classification Name	Gastroscope And Accessories, Flexible/Rigid
Regulation Number	876.1500
Product Code(s)	FDS, FET

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K954451	EVIS 140 SYSTEM	FET
K072957	Olympus CV-180/CLV-180	NWB

Device Description Summary

21 CFR 807.92(a)(4)

A. Intended Use/indications for Use
a) EG-S100XT
This product is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and 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) EG-S100XT
This product is upper gastrointestinal endoscope, is inserted into a lumen, coelom, body cavity, or the inside of the body to provide these regions images for observation, diagnosis, and treatment. This product is inserted through the oral. The flexible tube (hereinafter "the insertion tube") follows the figure of the upper gastrointestinal tract performing a bending operation. The tip of the endoscope reaches to the duodenum. It is used for observation, diagnosis, and treatment of the esophagus, stomach, and duodenum.
Insertion portion of this product has a mechanism (hereinafter "the bending section") which bends the tip from right to left and up and down, and the insertion tube consists of the bending section and operating portion with a knob which controls the bending section. The instrument channel which runs through the operating portion to the tip is arranged inside the insertion portion for inserting the endotherapy device. This product is a sterile, single-use device and not intended to be reprocessed.

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) EG-S100XT
The Endoscope Model EG-S100XT function on the same principles of operation as the predicate device.
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.
It is possible to do endoscopic fulguration, which enable a user to apply high-frequency electric current to objective regions inserting a high-frequency endotherapy device into the instrument channel of the operating portion.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) EG-S100XT
This product is intended for the visualization of the upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and 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) EG-S100XT
There is a difference in the description of the predicate device, however, there is no difference in the indication for use because the predicate device is also "something that provides images for the diagnosis and treatment of the esophagus, stomach, and duodenum".

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) EG-S100XT
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 EG-S100XT 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 EG-S100XT have differences in maximum insertion diameter and forceps channel diameter with predicate device, but these specifications is same as reference models. There are no new concerns for safety or efficacy.
As the difference of distal end diameter, flexible portion diameter and working length is 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 does not affect the safety or efficacy of the subject device. 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 subject 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 subject 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 data transport functions.
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 following performance for EG-S100XT was evaluated according to the engineering requirements listed in this section. In all cases, the devices met the pre-defined 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 Diameter (7) Field of view, (8)Viewing direction, (9)Resolution, (10)Visualization Brightness at Distances, (11)Color reproducibility

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 EG-S100XT is substantially equivalent to the predicate device and reference devices.