



August 7, 2026

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

Re: K260567

Trade/Device Name: EW10-EC02 Endoscopy Support Program
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulatory Class: Class II
Product Code: QNP
Dated: February 19, 2026
Received: February 19, 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), 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

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.

K260567

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Please provide the device trade name(s).

?

EW10-EC02 Endoscopy Support Program

Please provide your Indications for Use below.

?

This software is a computer-assisted reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. This software is used with standard WLI (White Light Imaging) and LCI (Linked Color Imaging) endoscopy imaging. This software is not intended to replace clinical decision making.

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](#))

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510(k) #: K260567

510(k) Summary

Prepared on: 2026-07-09

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	FUJIFILM Corporation
Applicant Address	798 Miyanodai Kaise-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	EW10-EC02 Endoscopy Support Program
Common Name	Gastrointestinal lesion software detection system
Classification Name	Gastrointesinal Lesion Software Detection System
Regulation Number	876.1520
Product Code(s)	QNP

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230751	EW10-EC02 Endoscopy Support Program	QNP

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

A. Intended Use/indications for Use

This software is a computer-assisted reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. This software is used with standard WLI (White Light Imaging) and LCI (Linked Color Imaging) endoscopy imaging. This software is not intended to replace clinical decision making.
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B. Device Description

There is an increasing interest in the application of artificial intelligence (AI) in health care to improve disease diagnosis, management, and the development of effective therapies. The remarkable development of AI from deep learning in recent years has increased the

possibility of machines assisting assessments by human visual observation. The subject device represents application of AI technology to endoscopic images to assist in detecting the presence of potential lesions. This development greatly contributes to improving the quality of colonoscopy. In recent years, computer-aided diagnosis (CAD) systems employing AI technologies have been approved and marketed as radiological medical devices for use with computed tomography (CT), X-ray, magnetic resonance imaging (MRI), and mammogram diagnostic images. In endoscopy as well, many images for diagnosis are taken. Since increasing the polyp detection rate is also in demand, CAD systems for endoscopy are being actively developed. Against this background, the company has developed this software (EW10-EC02), a new AI-based CAD system, to support Health Care Provider (HCP) detection of large intestine polyps in colonoscopic images. EW10-EC02 detects suspected large intestine polyps in the endoscope video image in real-time.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

This software is a computer-assisted reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. This software is used with standard WLI (White Light Imaging) and LCI (Linked Color Imaging) endoscopy imaging. This software is not intended to replace clinical decision making.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indication for use for the proposed device and the predicate devices are same.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

There is a difference in the compatible processor and endoscope between the subject device and the predicate device. Testing for the new compatible processor and endoscope was performed using the worst-case model specifications for the combination endoscope system, no new concerns for safety or efficacy was seen.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Verification and validation testing for the new compatible processor and endoscope was performed, no new concerns for safety or efficacy was seen.

Standalone Performance Testing was conducted in accordance with the same evaluation protocol as that used for the predicate device to assess the performance of the subject device. The results from object-level and frame-level assessments of more than 55 pre-recorded cases with EP-8000 processor demonstrated substantial equivalence to the predicate device.