September 26, 2025

Fujifilm Healthcare Americas Corporation
Kotei Aoki
Manager, Regulatory Affairs
81 Hartwell Ave.
Suite 300
Lexington, Massachusetts 02421

Re: K251204
Trade/Device Name: FUJIFILM Stiffening Wire Device (SW-2000)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDA
Dated: August 29, 2025
Received: August 29, 2025

Dear Kotei Aoki:

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)*
K251204

Device Name
FUJIFILM Stiffening Wire Device (SW-2000)

Indications for Use *(Describe)*
The intended use of the device is to allow the physician to increase the stiffness of the enteroscope when additional rigidity is required.
Do not use this product for any other purposes.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K251204

510(k) Summary

Prepared on: 2025-09-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FUJIFILM Healthcare Americas Corporation
Applicant Address	81 Hartwell Ave. Suite 100 Lexington MA 02421 United States
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Applicant Contact	Mr. Kotei Aoki
Applicant Contact Email	hcusregulatoryaffairs@fujifilm.com
Correspondent Name	FUJIFILM Healthcare Americas Corporation
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Correspondent Contact Telephone	781-323-5306
Correspondent Contact	Ms. Komal Patel
Correspondent Contact Email	hcusregulatoryaffairs@fujifilm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	FUJIFILM Stiffening Wire Device (SW-2000)
Common Name	Endoscope and accessories
Classification Name	Enteroscope And Accessories
Regulation Number	876.1500
Product Code(s)	FDA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K051068	ZUTRON COLONOSCOPE STIFFENING DEVICE	FDF

Device Description Summary

21 CFR 807.92(a)(4)

Predicate device selection:
The ZUTRON COLONOSCOPE STIFFENING DEVICE (K051068) was chosen as the predicate device. The predicate device was picked based on similar technological characteristics and performance when compared to the subject device. In accordance to draft guidance "Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission" the predicate device meets the best practices described in Section V of the guidance.

A. Intended Use/indications for Use
The intended use of the device is to allow the physician to increase the stiffness of the enteroscope when additional rigidity is required. Do not use this product for any other purposes.

B. Technological characteristics
The product consists of a nitinol wire of specific diameter and length that is centerless ground to create a tapered distal end that terminates in a ball tip. The tapered distal-end is meant to provide added flexibility to the product for ease of insertion into the endoscope, as well as reduced resistance to bending the angulation of the scope tip while in use. There is a metal tag at the proximal end of device that is use for gripping the device and setting the insertion length in the working channel of the endoscope.
The tag will also contain markings that identify the company name (Fujifilm), model number, dimensions, and Unique Device Identifier (UDI). The tag is assembled to the nitinol wire via mechanical means, such as a set screw that cannot be loosened or removed. The product will be packaged and sold in a non-sterile state.
The stiffening wire is designed to be contained within the endoscope instrument channel and not to protrude from the distal tip of the endoscope during use.

C. Principal of Operation
The FUJIFILM Stiffening Wire can be used for Retrograde double-balloon enteroscopy (DBE) and Antegrade DBE procedure.

For the Retrograde procedure once entry into the transverse colon is confirmed, withdraw the endoscope to straighten out the endoscope and instrument channel. Gently advance the stiffening wire device down the entire length of the instrument channel. If the stiffening wire does not advance with reasonable force, straighten the endoscope and retry. Advance endoscope to cecum and into ileum. Remove the stiffening wire device prior to endoscope withdrawal or at the physician's discretion.

For Antegrade procedure gently advance stiffening wire device down the desired length of the instrument channel. Position within the channel in the area corresponding to the segment of the endoscope that requires additional stiffness or straightening. Using DBE technique, advance the endoscope down the small intestine to the ileum. The physician at their discretion, will decide when to best use the stiffening wire device to aid in advancing to the ileum by adding endoscope stiffness to reduce looping and assist with the telescoping maneuvers of small bowel endoscopy. Remove the stiffening wire device prior to endoscope withdrawal or at the physician's discretion.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The intended use of the device is to allow the physician to increase the stiffness of the enteroscope when additional rigidity is required. Do not use this product for any other purposes.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The difference between the intended use of the subject device and predicate device does not raise new questions of safety or efficacy of the subject device. The predicate device is intended to be used with a colonoscope whereas the subject device is intended to be used with an enteroscope. All testing was conducted using an enteroscope and no new concerns for safety and efficacy was seen.

Technological Comparison

21 CFR 807.92(a)(6)

Fujifilm Stiffening Wire Device is compatible for FUJIFILM scopes EN-580T and EN-840T. Zutron Colonoscope Stiffening Device is compatible for FUJIFILM, Pentax, and Non-variable stiffness Olympus endoscopes. Although there are differences in the compatible endoscopes, the compatibility was tested during the design verification process and and no new concerns for safety and efficacy was seen. Compatible endoscopes are listed on the Operation Manual. Therefore, we believe the differences are minor and conclude that the subject device is as safe and effective as the predicate device.

The Fujifilm Stiffening Wire Device (SW-2000) demonstrates substantially equivalent performance to the Zutron Colonoscope Stiffening Device predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following performance for FUJIFILM Stiffening Wire device was evaluated. Testing was done for stiffness for each compatible endoscope.

(1) Compatible Scopes
(2) Endoscope Stiffness

The device met the pre-defined acceptance criteria listed in the test report.