



November 1, 2024

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

Re: K243091

Trade/Device Name: Over-tube (TR-1108A)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FED
Dated: September 30, 2024
Received: September 30, 2024

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 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

Indications for Use

Submission Number (if known)

K243091

Device Name

Over-tube (TR-1108A)

Indications for Use (Describe)

This product is intended to be used in combination with an endoscope to assist endoscopic insertion into the body. Never use this product for any other purpose. This product is intended for use in medical facilities by medical professionals who are properly trained in using it as well as in endoscopic procedures and endoscopic treatments.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Prepared on: 2024-09-27

Contact Details

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

Applicant Name	Fujifilm Corporation
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Applicant Contact	Ms. Chaitrali Kulkarni
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Correspondent Name	FUJIFILM Healthcare Americas Corporation
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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	Over-tube (TR-1108A)
Common Name	Endoscope and accessories
Classification Name	Endoscopic Access Overtube, Gastroenterology-Urology
Regulation Number	876.1500
Product Code(s)	FED

Legally Marketed Predicate Devices

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

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230752	Over-tube (TR-1208A)	FED

Device Description Summary

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

A. Intended Use/indications for Use

This product is intended to be used in combination with an endoscope to assist endoscopic insertion into the body. Never use this product for any other purpose. This product is intended for use in medical facilities by medical professionals who are properly trained in using it as well as in endoscopic procedures and endoscopic treatments.

Intended Use/Indications for Use[21 CFR 807.92\(a\)\(5\)](#)

This product is intended to be used in combination with an endoscope to assist endoscopic insertion into the body. Never use this product for any other purpose. This product is intended for use in medical facilities by medical professionals who are properly trained in using it as well as in endoscopic procedures and endoscopic treatments.

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 are size differences in the outer diameter, inner diameter, and maximum outer diameter. The differences in size do not affect the safety or efficacy of the device.

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

The changes in the subject device from the predicate device are changed in outer diameter, Inner diameter, Maximum outer diameter, insertion route, and combination endoscope. There were no changes to material, sterilization, or intended use. 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 Over-tube model is substantially equivalent to the predicate devices.

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

- Insertion Force
- Working length
- Flexibility
- Maximum diameter of insertion portion
- Outer diameter of insertion portion