September 15, 2023

Fujifilm Healthcare Americas Corporation
Kotei Aoki
Manager, Regulatory Affairs
81 Hartwell Avenue
Suite 300
Lexington, MA 02421

Re: K230752
Trade/Device Name: Over-tube (TR-1208A); Over-tube (TR-1504A); Over-tube (TR-1507A)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FED
Dated: March 17, 2023
Received: August 18, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230752

Device Name
Over-tube (TR-1208A);
Over-tube (TR-1504A);
Over-tube (TR-1507A)

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.

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510(k) #: K230752

510(k) Summary

Prepared on: 2023-08-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	FUJIFILM Healthcare Americas Corporation
Applicant Address	81 Hartwell Avenue, Suite 300 Lexington MA 02421 United States
Applicant Contact Telephone	7652462931
Applicant Contact	Mr. Kotei Aoki
Applicant Contact Email	kotei.aoki@fujifilm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Over-tube (TR-1208A); Over-tube (TR-1504A); Over-tube (TR-1507A)
Common Name	Endoscope and accessories
Classification Name	Endoscopic Access Overtube, Gastroenterology-Urology
Regulation Number	876.1500
Product Code	FED

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K191415	Pathfinder™ Endoscope Overtube	FED
K091773	FUJINON STERILE OVERTUBES	FED

Device Description Summary

21 CFR 807.92(a)(4)

FUJIFILM Over-tube consists of an insertion portion for inserting through the body, a handle portion to be gripped by the operator, a water injection portion for injecting water onto the inner wall of the insertion part, a suction portion for suctioning air from the walls, thereby changing the rigidity of the insertion part, and a hook portion for attaching to the control part of the endoscope. The suction portion is formed by a three-way stopcock and can be connected to a suction machine. The suction machine and changing the position of the three-way stopcock lever, the inside of the insertion portion can be in the state of vacuum, thereby increasing the rigidity of the insertion portion. The rigid body of the insertion portion maintains the shape of Over-tube and allow the endoscope insertion portion to smoothly move back and forth and rotate while decreasing the adverse impact to the patient anatomy. In addition, when water is injected from the water inlet connected to the inside of Over-tube, water enters between the endoscope and Over-tube, reducing friction between the endoscope and the Over-tube.

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)

Both the proposed devices and the predicate device are combined with the compatible endoscope and assist the endoscope to be used in the patient's gastrointestinal tract. Both devices are indicated for adult patients only. The indications for use and intended use are the same in the proposed devices and the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The inner diameters of the proposed devices are smaller than that of the predicate device. The insertion force of the compatible endoscope through the proposed devices has been evaluated through the bench testing. There is no new concern for the safety and efficacy of the proposed devices.

The maximum outer diameter of the predicate device is unknown. The working lengths of the proposed devices are different from that of the predicate device. Thus, the maximum outer diameters and the working lengths of the proposed devices have been evaluated through the bench testing. There is no new concern for the safety and efficacy of the proposed devices.

The compatible endoscopes are different the predicate device. The bench testing demonstrates that there is no new concern for the safety and efficacy of using the proposed devices with respective compatible endoscopes.

The connectors of the water and air inlets in the predicate device is unknown. However, the Luer connectors of the water and air inlets in the proposed device are the same as the Luer connection of the water and air inlets in the Reference Device FUJINON STERILE OVERTUBE TS-13101 (K091773). Therefore, there is no new concern for the safety and effectiveness regarding the connectors of the water and air inlets.

The transport and storage environment of the predicate device is unknown. The transport and storage environment of the proposed devices has been evaluated through the long-term stability testing. There is no new concern for the safety and efficacy of the proposed devices when they are properly transported and stored.

The material construction of the predicate device is unknown. The material construction of the proposed devices has been evaluated through the biocompatibility testing. There remains no new concern for the safety and efficacy.

The proposed Over-tubes and the predicate device, Pathfinder™ Endoscope Overtube GI 085160-2 (K191415), share the same intended use and indications. The proposed device and the predicate device share some technological characteristics and principles of operation. The biocompatibility testing and bench testing demonstrate that the proposed devices remain as safe and effective as the predicate device. The proposed Over-tubes are substantially equivalent to the predicate Overtube.

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

Insertion force, working length, flexibility, shape retention, maximum diameter of insertion portion, and outer diameter of insertion portion were tested on Over-tube models TR-1208A and TR-1507A as the representative model. TR-1504A only differs from TR-1507A in working length only (see "bench testing.pdf"). Since TR-1507A is longer than TR-1504A, TR-1504A can adopt the performance of TR-1507A.

The durability of the main body of the proposed device was evaluated with the accelerated-aged Over-tube TR-1208A to ensure there were no adverse effects on the appearance, insertion force, hardness when hardened, attachable to the operating portion, and durability under tension (see "Long-term Stability Test Rep.pdf").

The safety of sterilized packaging was evaluated with the accelerated-aged device Over-tube TR-1507A to ensure there were no adverse effects on the appearance, seal strength, and dye penetration (see "Long-term Stability Test Rep.pdf").

Not Applicable

The testing demonstrated that the devices met the design requirements. Furthermore, the accelerated-aged testing supports the 3-year shelf life of the devices.