June 13, 2024

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

Re: K233321
Trade/Device Name: Double Balloon Endoscope EN-840T, Over-tube TS-1214C
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDA
Dated: May 14, 2024
Received: May 14, 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.

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233321

Device Name

Double Balloon Endoscope EN-840T;
Over-tube TS-1214C

Indications for Use *(Describe)*

Double Balloon Endoscope Model EN-840T
This device is intended for the visualization of the upper and lower digestive tracts, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, duodenum, small intestine, large intestine and rectum.
Never use this product for any other purposes.

Over-Tube TS-1214C
This product is intended to be used as an accessory with the FUJIFILM Double Balloon Endoscope cleared for use with an Over-tube. The Over-tube is used to assist with the movement of the scope inside the upper or lower digestive tract. This product is not intended for use for any neonates, infants or children.

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) #: K233321

510(k) Summary

Prepared on: 2024-06-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Fujifilm Healthcare Americas Corporation
Applicant Address	81 Hartwell ave Suite 300 Lexington MA 02421 United States
Applicant Contact Telephone	704-517-4886
Applicant Contact	Ms. Chaitrali Kulkarni
Applicant Contact Email	chaitrali.kulkarni@fujifilm.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Double Balloon Endoscope EN-840T; Over-tube TS-1214C
Common Name	Endoscope and accessories
Classification Name	Enteroscope And Accessories
Regulation Number	876.1500
Product Code	FDA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K143556	Fujifilm Double Balloon Endoscopes Models EN-530T and EN-58	FDA
K221551	FUJIFILM Endoscope Model EI-740D/S	FDS
K183032	FUJIFILM Double Balloon Endoscope EI-580BT	FDA
K223295	Endoscope Model EN-580T, Over-tube TS-1314B, Balloon BS-4	FDA

Device Description Summary

21 CFR 807.92(a)(4)

Technological characteristics

a. Double Balloon Endoscope Model EN-840T
The insertion portion of the device has a mechanism (hereinafter "the bending portion") which bends the tip from right to left and up and down, and a flexible tube (hereinafter "the flexible portion") consists of the bending portion and operating portion with a knob which controls the bending portion. The forceps channel which runs through the operating portion to the tip is arranged inside the insertion portion for inserting the surgical instrument.

The insertion portion of the endoscopes comes into contact with the mucosal membrane.

The tip of the insertion portion is called the "Distal end" which contains the Imaging section, Balloon air feed outlet , Distal cap, Objective lens, Air/water nozzle, Water jet nozzle, Instrument channel outlet, Objective lens, and Light guide.

The bending portion is controlled by knobs on the control portion/operation section to angulate the distal end to certain angles.

The Flexible portion refers to the long insertion area between the Bending portion and the Control portion (a part of Non-insertion portion). This portion contains light guides (glass fiber bundles), air/water channels, a forceps/suction channel, a CMOS image sensor, and cabling. The glass fiber bundles allow light to travel through the endoscope to illuminate the body cavity, thereby providing enough light to the CMOS sensor to capture an image and display the image on a monitor. The forceps channel is used to introduce biopsy forceps and other endoscopic accessories, as well as providing suction.

The control portion/operating section provides a grip to grasp the endoscopes and contains mechanical parts to operate the endoscopes. This section includes a Forceps inlet, which allows endoscope accessories to be introduced. The Scope connector connects the endoscopes to the light source.

b. Over-tube TS-1214C

The over-tube TS-1214C is introduced in the patient's anatomy with the pairing endoscope. TS-1214C is assembled over the outer diameter of endoscope. The endoscope and the over-tube are not advanced both at the same time, but alternatingly and successively. TS-1214C is provided sterile and single-patient use only. This accessory is a Class 2 device.

Principles of Operation

a. Double Balloon Endoscope Model EN-840T

The Double Balloon Endoscope Model EN-840T function on the same principles of operation as the predicate device. EN-840T is a gastrointestinal endoscope for observation, diagnosis, and treatment of the upper and lower digestive tract. After connecting to the light source, the devices guide the light through the fiber bundles situated inside the insertion portion of the device. The light that emits from the distal end of the insertion portion reflects from the target region and forms an image on the CMOS image sensor through a group of object lenses placed at the distal end of the devices. An electric signal from the image sensor is transmitted to the video processor connected to the device. The video processor converts the electric signal into a video signal and displays an image on a monitor.

b. Over-tube TS-1214C

An over-tube is attached to the insertion portion of the endoscope, and then the scope balloon is mounted to the distal end of the endoscope using the specified setting tool.

By inflating the balloon at distal end of the over-tube and the balloon at the distal end of the endoscope, the distal end of the over-tube and the distal end of the endoscope are maintained in the body cavity.

By inserting an over-tube after the endoscope, it is possible to correct the hollow viscera. And then by inflating a balloon attached to the distal end of the over-tube, the distal end is fixed and consequently stronger straightening of the hollow viscera can be obtained.

Intended Use/Indications for Use — 21 CFR 807.92(a)(5)

Double Balloon Endoscope Model EN-840T
This device is intended for the visualization of the upper and lower digestive tracts, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, duodenum, small intestine, large intestine and rectum.
Never use this product for any other purposes.

Over-Tube TS-1214C
This product is intended to be used as an accessory with the FUJIFILM Double Balloon Endoscope cleared for use with an Over-tube. The Over-tube is used to assist with the movement of the scope inside the upper or lower digestive tract. This product is not intended for use for any neonates, infants or children.

Indications for Use Comparison — 21 CFR 807.92(a)(5)

The proposed overtube and double balloon have the same intended use as the predicate devices.

Technological Comparison — 21 CFR 807.92(a)(6)

The proposed Over-tube has two side holes on the insertion portion. The holes were added to be able to discharge air trapped between

the Over-tube and the body cavity from the endoscope insertion inlet to the outside of the body. The addition of the two side holes does not affect the safety or efficacy of the device.

The proposed Over-tube has an additional compatible endoscope to use in combination with the over-tube. The endoscope has been tested to be compatible with the over-tube and there are no new concerns for safety or efficacy.

The balloon material on the proposed Over-tube is different than the predicate devices. Biocompatibility testing has been conducted, there are no new concerns for safety or efficacy.

The proposed endoscope has a CMOS image sensor, the predicate devices have CCD. The difference in the image sensor does not affect the safety or efficacy of the proposed endoscope.

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

EMC and Electrical safety of the subject device was evaluated using following standards: ANSI/AAMI ES ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), IEC 60601-1-2:2020, IEC 60601-1-6:2013, and IEC 60601-2-18:2009.

Biocompatibility of the subject device was evaluated using the following consensus standards: ISO 10993-1:2018, ISO 10993-5:2009, and ISO 10993-10:2010. Biocompatibility testing was performed in accordance with FDA's guidance, Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process', issued September 4, 2020.

Endoscope specific testing was conducted using the following consensus standards: ISO 8600-1:2015, ISO 8600-3:1997, and ISO 8600-4:2014.

The proposed EN-840T is provided non-sterile and must be reprocessed prior to each use. Sterility of the other new accessories TS-1314B and BS-4 were evaluated using the following consensus standards: ISO 11135:2014, ISO 10993-7:2008, ISO 11607-1:2019, ISO 11607-2:2019, ISO 11737-1:2018, and ISO 11138-1:2017. Sterilization validation was performed in accordance with FDA's guidance, Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, issued January 21, 2016.

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

- Field of view
- Diameter of forceps channel
- Bending capability
- Viewing direction
- Rate of suction
- Resolution
- Working length
- LG output

The subject devices Double Balloon Endoscope EN-840T and Over-tube TS-1214C are substantially equivalent to the predicate devices based on the same intended use, indications for use, similar technological characteristics and materials. The differences in technological characteristics and materials between the subject and predicate devices raise no new issues of safety or effectiveness. Bench testing data demonstrated that the subject devices are substantially equivalent in performance to the predicate devices. The difference in materials between subject and predicate devices has been validated through biocompatibility testing. Thus, Double Balloon Endoscope EN-840T and Over-tube TS-1214C the subject devices are substantially equivalent to the predicate devices, Fujifilm Double Balloon Endoscope Model EN-580T and Over-tube TS1314B (K223295).