January 11, 2023

FUJIFILM Corporation
% Kotei Aoki
Senior Regulatory Affairs Specialist
FUJIFILM Healthcare Americas Corporation
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K223295
Trade/Device Name: Endoscope Model EN-580T, Over-Tube TS-1314B, Scope Balloon BS-4, Tube Kit TY-500D
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Codes: FDA, FDF
Dated: December 12, 2022
Received: December 12, 2022

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)*
K223295

Device Name
Endoscope EN-580T, Over-tube TS-1314B, Balloon BS-4, Tube Kit TY-500D

Indications for Use *(Describe)*

Endoscope EN-580T
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-1314B
This product is used in combination with a FUJIFILM Double Balloon Endoscope to assist the insertion of the Endoscope under the management of physicians in medical facilities.
This product is used to assist with the movement of the scopes inside the upper or lower digestive tract.
Do not use this product for any other purposes.
This product is not intended for use for any neonates, infants or children.

Balloon BS-4
This product is used in combination with FUJIFILM Double Balloon Endoscopes at medical facilities under the management of physicians.
Being attached to the endoscope, this product is inserted into the digestive tract from the mouth or anus to stabilize the distal end of the endoscope to the digestive tract`s mucous membrane.
Do not use this product for any other purposes.
This product is not intended for use for any neonates, infants or children.

Tube Kit TY-500D
This product is the tube kit used in combination with the compatible balloon controller in medical facilities.
Do not use this product for any other purpose.

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.

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510(k) Summary

FUJIFILM Corporation

Endoscope EN-580T, Over-tube TS-13140, Balloon BS-3, Tube Kit TY-06D

January 6, 2023

Submitter's Information:
FUJIFILM Corporation
798 MIYANODAI KAISEI-MACHI
ASHIGARAKAMI-GUN, KANAGAWA
258-8538 JAPAN

Contact Person:
Kotei Aoki
Senior Regulatory Affairs Specialist
E-Mail: kotei.aoki@fujifilm.com
Telephone: (765) 246-2931

Identification of the Proposed Device:

Device Names:	Endoscope EN-580T, Over-tube TS-13140, Balloon BS-3, Tube Kit TY-06D
Common Names:	Endoscope, Accessories
Product Codes:	FDA, FDF
Device Class:	Class II
Regulation Number:	21 CFR 876.1500
Regulation Description:	Endoscope and Accessories
Review Panel:	Gastroenterology/Urology

Predicate Device(s):

- FUJIFILM Double Balloon Endoscope EN-580T (K183683)
- Over-tube TS-13140 (K143556)
- Balloon BS-3 (K213195)
- Tube Kit TY-06D (K143556)

Intended Use / Indications for Use:

Endoscope EN-580T
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-1314B
This product is used in combination with a FUJIFILM Double Balloon Endoscope to assist the insertion of the Endoscope under the management of physicians in medical facilities.
This product is used to assist with the movement of the scopes inside the upper or lower digestive tract.
Do not use this product for any other purposes.
This product is not intended for use for any neonates, infants or children.

Balloon BS-4
This product is used in combination with FUJIFILM Double Balloon Endoscopes at medical facilities under the management of physicians.
Being attached to the endoscope, this product is inserted into the digestive tract from the mouth or anus to stabilize the distal end of the endoscope to the digestive tract`s mucous membrane.
Do not use this product for any other purposes.
This product is not intended for use for any neonates, infants or children.

Tube Kit TY-500D
This product is the tube kit used in combination with the compatible balloon controller in medical facilities.
Do not use this product for any other purpose.

Device Description:

The endoscope EN-580T is inserted both perorally and transanally into the gastrointestinal tract during clinical use. The insertion portion of the device has a mechanism which bends the tip from right to left and up and down, and a flexible tube 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 over-tube TS-1314B is introduced in the patient's anatomy with the pairing endoscope. TS-1314B 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-1314B is provided sterile and single-patient use only.

The balloon BS-4 is attached to the distal end of the balloon-compatible endoscope. The balloon air feed outlet should be contained inside BS-4. The accompanying fixing rubber is used to affix the scope balloon in place. The fixing rubbers are made specifically for BS-4 but should not be mixed with the fixing rubber of other scope balloons. BS-4 is provided sterile and single-patient use only.

The tube kit TY-500D consists of a set of two tubes. One of the tubes connects the over-tube to the balloon controller by its air inlet. The other tube connects the same balloon controller to the endoscope by its balloon air feed inlet. TY-500D is only compatible with PB-30, cleared K153483. TY-500D is provided non-sterile. The tubes are not patient-contacting and reusable, but each filter is single-patient use only.

Comparison of Technological Characteristics:

The proposed EN-580T differs from the predicate EN-580T in terms of the compatible accessories. The modifications are also proposed in some technical characteristics and the material construction of the said accessories. The proposed device and the predicate device share the same intended use, principle of operation, and other technical characteristics of the compatible accessories. A summary of modifications is provided below.

A comparison of technological characteristics between the proposed device and the predicate device is provided in Table 1 through Table 6:

Table 1 Comparison of endoscopes – compatible accessories

	Proposed Device **Endoscope** **EN-580T (K223295)**	**Predicate Device** FUJIFILM Double Balloon Endoscope EN-580T (K183683)
Intended Use	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.	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-13140 TS-1314B (proposed)	TS-13140
Scope Balloon	BS-2, BS-3 BS-4 (proposed)	BS-2, BS-3
Balloon Controller	PB-30	PB-20, PB-30
Tube Kit	TY-06D [1] TY-500D (proposed) [2]	TY-06D [1]

[1] TY-06D should be paired only with TS-13140.
[2] TY-500D should be paired only with TS-1314B.

Table 2 Comparison of over-tubes

		Proposed Device **Over-tube TS-1314B (K223295)**	**Predicate Device** Over-tube TS-13140 (K143556)
Intended Use		This product is used in combination with a FUJIFILM Double Balloon Endoscope to assist the insertion of the Endoscope under the management of physicians in medical facilities. This product is used to assist with the movement of the scopes inside the upper or lower digestive tract. Do not use this product for any other purposes. This product is not intended for use for any neonates, infants or children.	These sterile Over-tubes are intended to be used as accessories with the FUJINON/FUJIFILM Double Balloon Endoscopes cleared for use with Over-tubes. The Over-tubes are used to assist with the movement of the scopes inside the upper or lower digestive tract. This product is not intended for use for any neonates, infants or children.
Working length / Total length		1350mm / 1450mm	
Insertion portion (diameters) (inner/outer/outer maximum)		10.8mm/13.2mm/16mm	
Outer diameter of balloon		40mm	
Working length of balloon		50mm	
Provided sterile		Yes, EO Sterilized	
Reuse		No, Single patient use only	
Product expiration		3 years	2 years
Connector type	Water inlet	Luer connector (Female)	
	Air inlet	Luer connector (Male)	Luer connector (Female)
Transport and storage Environment		Temperature: -10 to +60°C Humidity: 30 to 95% (no condensation) Atmosphere: 70 to 106 kPa	Temperature: +10 to +40°C Humidity: 30 to 85% (no condensation) Atmosphere: 70 to 106 kPa

Table 3 Comparison of balloons

	Proposed Device **Balloon BS-4 (K223295)**	**Predicate Device** Balloon BS-3 (K213195)
Intended Use	This product is used in combination with FUJIFILM Double Balloon Endoscopes at medical facilities under the management of physicians. Being attached to the endoscope, this product is inserted into the digestive tract from the mouth or anus to stabilize the distal end of the endoscope to the digestive tract's mucous membrane. Do not use this product for any other purposes. This product is not intended for use for any neonates, infants or children.	Balloon BS-3 is intended to be used in combination with FUJIFILM double balloon endoscopes to assist with insertion inside the upper or lower digestive tract at medical facilities under the management of physicians. Do not use this product for any other purpose. It is not intended for use for any neonates, infants or children.
Outer diameter	35mm	
Thickness	0.25mm	0.10mm
Working length / Total length	50mm / 66mm	40mm / 60mm
Provided sterile	Yes, EO Sterilized	
Reuse	No, Single patient use only	
Product expiration	3 years	2 years
Transport and storage Environment	Temperature: -10 to +60°C Humidity: 30 to 95% (no condensation) Atmosphere: 70 to 106 kPa	Temperature: +10 to +40°C Humidity: 30 to 85% (no condensation) Atmosphere: 70 to 106 kPa

Table 4 Comparison of tube kits

		Proposed Device **Tube Kit TY-500D (K223295)**	**Predicate Device** Tube Kit TY-06D (K143556)
Intended Use		This product is the tube kit used in combination with the compatible balloon controller in medical facilities. Do not use this product for any other purpose.	This product is the tube kit used in combination with the balloon controller PB-20 in medical facilities. Do not use this product for any other purpose.
Working length	Over-tube side	2050mm	
	Scope side	1300mm	
Connector type	Balloon controller side	Luer connector (Female)	
	Over-tube side	Luer connector (Female)	Luer connector (Male)
	Scope side	Dedicated connector	
Provided sterile		No	
Reuse		Tube: Yes Filter: No, Single patient use only	
Transport and storage Environment		Temperature: -10 to +45°C Humidity: 30 to 95%RH (no dew condensation) Atmosphere: 70 to 106 kPa	

Table 5 Material construction comparison of the over-tubes

	Proposed Device **Over-tube TS-1314B (K223295)**	**Predicate Device** Over-tube TS-13140 (K143556)	**Contact type**
Balloon	Silicone rubber (LSR 2030)	Natural rubber (Fujilatex DPNR) ABSORBO HP	Direct
Adhesive potion	**Bond**: Silicon series adhesive agent **Adhesive coat**: Silicon series adhesive agent (Compound ratio A:B = 5:1) A) Silicon Rubber (YE3085) B) Silicon Sealing Agent (KE-42-T)	**Bond**: Silicone compound (KE445B) **Adhesive coat**: N/A	[1]
Tube	**Tube**: Silicon rubber (ELASTOSIL WS 9802 C) **Coating**: Polyvinylpyrrolidone (K Value:90)	**Tubing**: Polyurethane (E380MNAT) **Coating**: Polyvinylpyrrolidone (Kollidon 30)	Direct
Tip Ring	Silicon rubber (Compound ratio C:D = 1:1) C) Silicon Rubber (ELASTOSIL R 401/90 OH) D) Silicon Rubber w/ Barium Sulfate (ELASTOSIL EL 7704)		Direct
Handle	**Handle**: Silicon rubber (ELASTOSIL WS 9802 C) **Coating**: Polyvinylpyrrolidone (K Value:90)		Indirect
Check Valve	Silicon rubber (ELASTOSIL WS 9402 C)		Indirect
Water feed inlet	Silicon rubber (ELASTOSIL WS 9802 C)		Indirect
Endoscope Insertion inlet	Silicon rubber (ELASTOSIL WS 9402 C) Polyvinylpyrrolidone (K Value:90)		Indirect

[1] In the adhesive portion of the predicate device, the bonded portion is not coated and considered "Direct" contact type. On the other hand, the adhesive portion of the proposed device is coated. Consequently, the bonded portion is not patient contacting while the coating over the bonded portion is considered "Direct" contact type.

Table 6 Material construction comparison of the balloons

	Proposed Device **Balloon BS-4 (K223295)**	**Predicate Device** Balloon BS-3 (K213195)	**Contact type**
Balloon	Silicone rubber (LSR 2030)	Natural rubber (Fujilatex DPNR)	Direct
		ABSORBO HP	Direct
Fixing rubber	Silicone rubber (ELASTOSIL WS 9502 C)	Natural rubber (Fujilatex DPNR)	Direct
		ABSORBO HP	Direct

Performance Data:

Sterility of TS-1314B and BS-4 were evaluated using the following consensus standards: ISO 11135:2014, ISO 10993-7:2008/AMD1:2019, ISO 11607-1:2019, ISO 11607-2:2019, ISO 11737-1:2018, and ISO 11138-1:2017.

The new accessories are made of different materials compared to the respective predicate devices. Biocompatibility of each new accessory was evaluated using the following consensus standards: ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, and ISO 10993-12:2012. 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 according to ISO 8600-1:2015, ISO 8600-3:2019, and ISO 8600-4:2014. Endoscope compatibility with the new accessories was conducted with acceptable results.

Conclusions:

The proposed devices Endoscope EN-580T, Over-tube TS-13140, Balloon BS-3, and Tube Kit TY-06D shares the same intended use as the respective predicate devices. The endoscope's compatibility with the new accessories was evaluated. The differences among the accessories and their respective predicate devices have been evaluated for the biocompatibility and bench testing with acceptable results. Thus, the proposed device Endoscope EN-580T, Over-tube TS-13140, Balloon BS-3, and Tube Kit TY-06D are substantially equivalent to the respective predicate devices, FUJIFILM Double Balloon Endoscope EN-580T (K183683), Over-tube TS-13140 (K143556), Balloon BS-3 (K213195), and Tube Kit TY-06D (K143556).