October 29, 2021

FUJIFILM Corporation
% Jeffrey Wan
Manager, Regulatory Affairs
FUJIFILM Healthcare Americas Corporation
81 Hartwell Avenue, Suite 300
Lexington, MS 02421

Re: K213195
Trade/Device Name: Balloon BS-3
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDA
Dated: September 29, 2021
Received: September 29, 2021

Dear Jeffrey Wan:

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, 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)*
K213195

Device Name

Balloon BS-3

Indications for Use *(Describe)*
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.

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) SUMMARY
FUJIFILM Corporation
Balloon BS-3
K213195

Date: October 18, 2021

Submitter's Information:
FUJIFILM Corporation
798 Miyanodai Kaisei-Machi
Ashigarakami-Gun, Kanagawa, 258-8538, Japan

Contact Person:
Jeffrey Wan
Manager, Regulatory Affairs
Telephone: (201) 675-8947
E-Mail: jeffrey.wan@fujifilm.com

Identification of the Proposed Device:

Device Name:	Balloon BS-3
Common Name:	Endoscopic Accessory
Device Class:	Class II
Classification Number:	21 C.F.R. § 876.1500
Classification Name:	Endoscope and accessories
Device Panel:	Gastroenterology/Urology
Product Code:	FDA

Predicate Devices:

- Balloon BS-2 (K143556)

Intended Use / Indications for Use

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.

Device Description

Balloon BS-3 is a pre-sterilized, single-use accessory used for fixing the endoscope in the body cavity. The device is fixed at the tip or bending portion of the endoscope and is inflated by filling air from the operation part of the endoscope with a special pump. The device is used for a natural opening of the

human body to perform enlargement of a lumen, coelom or body cavity in order to enable and facilitate insertion of the endoscope.

Comparison of Technological Characteristics

A comparison of technological characteristics between BS-3 and the predicate BS-2 is provided below:

	Subject Device **BS-3**	**Predicate Device** **BS-2**
510(k) number	To be assigned	K143556
Product code	FDA	FDA
Manufacturer	FUJIFILM Corporation	FUJIFILM Corporation
Intended Use	This product 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.	The balloon is intended to be used in combination with Double Balloon Endoscopes to assist with insertion inside the upper or lower digestive tract. This product is not intended for use for any neonates, infants or children.
Outer diameter	35mm	35mm
Film thickness	0.10mm	0.10mm
Working length	40mm	40mm
Total length	60mm	60mm
Compatible endoscopes	EN-580T EI-580BT	EN-450P5/20 EN-450T5 EC-450BI5 EN-580T EI-580BT
Sterile method	EO	Non sterile
Single use	Yes	Yes

Performance Data

Sterility of the subject devices was evaluated using the following consensus standards: ISO 11135:2014 and ASTM F1980-16.

Biocompatibility of the subject device was evaluated using the following consensus standards:

ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-7:2008, 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,'" published September 4, 2020.

Comparative bench testing was conducted on the subject and predicate devices to evaluate the rate of inflation. The subject device was additionally evaluated against ISO 8600-1:2015.

Conclusions

The subject device Balloon BS-3 shares the same intended use and similar indications as the predicate device. Bench testing demonstrates that the subject device is as safe and effective as the predicate device. Thus, Balloon BS-3 is substantially equivalent to the listed predicate device.