October 30, 2020

Fujifilm Corporation
% Jeffrey Wan
Senior Regulatory Affairs Specialist
FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K203028
Trade/Device Name: FUJIFILM Distal End Cap
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDT
Dated: September 30, 2020
Received: October 2, 2020

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, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203028

Device Name

FUJIFILM Distal End Cap DC-08D

Indications for Use *(Describe)*

This product is a single use distal end cap required to be attached to certain FUJIFILM endoscopes during clinical use to assist in providing atraumatic passage of the endoscope tip during endoscopic procedures.

Do not use this product for any other purposes.

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
Distal End Cap DC-08D

Date: September 30, 2020

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

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

Identification of the Proposed Device:

Device Name:	FUJIFILM Distal End Cap DC-08D
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 Information:

Product Code Name:	Duodenoscope and accessories, flexible/rigid
CFR Section:	21 CFR 876.1500
Product Code:	FDT

Predicate Device:

- FUJIFILM Distal End Cap DC-07D (K191747)

Intended Use / Indications for Use

This product is a single use distal end cap required to be attached to certain FUJIFILM endoscopes during clinical use to assist in providing atraumatic passage of the endoscope tip during endoscopic procedures.

Do not use this product for any other purposes.

Device Description

FUJIFILM Distal End Cap DC-08D is a single use device that is supplied sterile, eliminating the need for reprocessing prior to use. This distal end cap is designed to be attached to the distal tip of a FUJIFILM ED-580XT duodenoscope. After an endoscopic procedure, the DC-08D is detached to facilitate easier access to the distal elevator during reprocessing of the ED-580XT.

Comparison of Technological Characteristics

The subject device FUJIFILM Distal End Cap DC-08D differs from the predicate device in the following modifications:

- DC-08D is supplied sterile, while DC-07D is supplied non-sterile and requires reprocessing prior to use.
- Packaging change from non-sterile bag to sterile pouch
- Material change

Performance Data

Sterility of the subject device was evaluated using the following consensus standards: ASTM F1980-16, ISO 11137-1:2006, ISO 11607-1:2019, ISO 11607-2:2019.

Biocompatibility of the subject device was evaluated using the following 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,'" published June 16, 2016.

Bench testing was conducted to demonstrate that the subject device is attached securely such that it will not detach during use.

The subject device was evaluated for conformance to ISO 8600-1:2015. Additional performance specifications were evaluated against pre-determined acceptance criteria.

Conclusions

The subject device DC-08D shares the same intended use and indications to the predicate device. Bench testing demonstrates that the subject device is as safe and effective as the predicate device. Thus, DC-08D is substantially equivalent to the listed predicate device.