August 19, 2021

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

Re: K212296
Trade/Device Name: Distal Cap Model DH-32EN, Distal Cap Model DH-17EN2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDF, FDS
Dated: July 21, 2021
Received: July 22, 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 control's 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,

for
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)*
K212296

Device Name

Distal Cap Models DH-32EN and DH-17EN2

Indications for Use *(Describe)*
Distal Cap Models DH-32EN and DH-17EN2 are intended to be used in combination with the dedicated endoscope to maintain the field of view during endoscopic procedures.

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.

510(k) SUMMARY
FUJIFILM Corporation
Distal Cap Models DH-32EN and DH-17EN2

Date: July 21, 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:	Distal Cap Models DH-32EN and DH-17EN2
Common Name:	Endoscopic Accessory
Device Class:	Class II
Classification Number:	21 C.F.R. § 876.1500
Classification Name:	Endoscope and accessories
Device Panel:	Gastroentereology/Urology
Product Code:	FDS, FDF

Predicate Devices:

- Distal Cap Model DH-39CZ (K193123)

Intended Use / Indications for Use

Distal Cap Models DH-32EN and DH-17EN2 are intended to be used in combination with the dedicated endoscope to maintain the field of view during endoscopic procedures.

Device Description

Distal Cap Models DH-32EN and DH-17EN2 are pre-sterilized, single-use accessories that are attached to the tip of an applicable FUJIFILM double balloon endoscope to maintain a clear, unobstructed field of view during endoscopic procedures.

Comparison of Technological Characteristics

A comparison of technological characteristics between DH-32EN and DH-17EN2 and the predicate DH-39CZ is provided below:

	Subject Device #1 DH-32EN	**Subject Device #2 DH-17EN2**	**Predicate Device DH-39CZ**
510(k) number	To be assigned	To be assigned	K193123
Product code	FDF, FDS	FDF, FDS	FDF, FDS
Manufacturer	FUJIFILM Corporation	FUJIFILM Corporation	FUJIFILM Corporation
Intended Use	Distal Cap Models DH-32EN and DH-17EN2 are intended to be used in combination with the dedicated endoscope to maintain the field of view during endoscopic procedures.	Distal Cap Models DH-32EN and DH-17EN2 are intended to be used in combination with the dedicated endoscope to maintain the field of view during endoscopic procedures.	This hood is intended to be used in combination with compatible endoscopes to maintain the field of view during observation of the digestive tract
Outer diameter	9.7±0.2mm	11.5±0.2mm	14.2±0.5mm
Maximum diameter of compatible endoscope	13.3mm	17.8mm	18.2mm
Total length	9.1mm	8.0mm	12.0mm
Distance from the tip	1.3mm	1.5mm	2.0mm
Compatible endoscopes	EN-580T EI-580BT	EN-580T EI-580BT	EC-600HL
Sterile method	EO	EO	EO
Single use	Yes	Yes	Yes

Performance Data

Sterility of the subject devices was evaluated using the following consensus standards: ISO 11135:2014, ISO 11607-1:2019, 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.

Bench testing was conducted to demonstrate that the subject devices are attached securely such that they will not detach during use.

Additional performance specifications were evaluated against pre-defined acceptance criteria.

Conclusions

The subject devices Distal Cap Models DH-32EN and DH-17EN2 share the same intended use and similar indications to the predicate device. Bench testing demonstrates that the subject devices are as safe and effective as the predicate device. Thus, Distal Cap Models DH-32EN and DH-17EN2 are substantially equivalent to the listed predicate device.