February 4, 2022

FUJIFILM Corporation
% Dhara Buch
Regulatory Affairs Specialist
FUJIFILM Healthcare Americas Corporation
81 Hartwell Avenue, Suite 300
Lexington, MA 02421

Re: K220053
Trade/Device Name: Diathermic Slitter (FlushKnife) DK2620JI and DK2623JI
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KGE
Dated: January 5, 2022
Received: January 6, 2022

Dear Dhara Buch:

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)*
K220053

Device Name
FUJIFILM Diathermic Slitter (FlushKnife) DK2620JI and DK2623JI

Indications for Use *(Describe)*
These products are used in combination with an applicable endoscope to perform the endoscopic treatments for the target site in the gastrointestinal tract, such as ablation, incision, dissection, cauterization, coagulation and avulsion of tissue and arrest of bleeding, and to inject saline or submucosal injection agent for endoscopic surgery into the submucosal layer in the gastrointestinal tract, which is exposed after dissection, under the management of physicians in medical facilities. Never 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

FUJIFILM Corporation

FUJIFILM Diathermic Slitter (FlushKnife) DK2620JI and DK2623JI

Date: January 05, 2021

Submitter's Information:

FUJIFILM Corporation
798 Miyanodai Kaisei-Machi
Ashigarakami-Gun, Kanagawa, 258-8538, Japan

Contact Person:

Dhara Buch
Regulatory Affairs Specialist
Phone: 781-824-2708
E-Mail: dhara.buch@fujifilm.com

Identification of the Proposed Device:

Device Name:	FUJIFILM Diathermic Slitter (FlushKnife) DK2620JI and DK2623JI
Common Name:	Electrosurgical Instruments
Product Code:	KGE
Device Class:	Class II
Classification:	Endoscopic electrosurgical unit and accessories 21 C.F.R. § 876.4300
Review Panel:	Gastroenterology/Urology

Predicate Device:

- FUJIFILM Diathermic Slitter FlushKnife (K171096)

Intended Use / Indications for Use:

These products are used in combination with an applicable endoscope to perform the endoscopic treatments for the target site in the gastrointestinal tract, such as ablation, incision, dissection, cauterization, coagulation and avulsion of tissue and arrest of bleeding, and to inject saline or submucosal injection agent for endoscopic surgery into the submucosal layer in the gastrointestinal tract, which is exposed after dissection, under the management of physicians in medical facilities. Never use this product for any other purpose.

Device Description:

FUJIFILM Diathermic Slitter (FlushKnife) is an electrosurgical instrument that removes tissue and controls bleeding by use of high-frequency ("HF") electrical current. The device is available with either a needle or ball tip slitter and comes in a variety of sizes.

Comparison of Technological Characteristics:

A comparison of technological characteristics between subject device and the predicate device is provided table below:

Device Details	Predicate Device	Subject Device
Device Name	FUJIFILM Diathermic Slitter Knife	FUJIFILM Diathermic Slitter (FlushKnife) DK2620JI and DK2623JI
Model	MODEL DK2618J -N10-, DK2618J -N15-, DK2618J -N20-, DK2618J -N25-, DK2618J -N30-, DK2618J -B15-, DK2618J -B20-, DK2618J -B25-, DK2618J -B30-, DK2623J -N15-, DK2623J -N20-, DK2623J -B15-, DK2623J -B20-	MODEL DK2620JI N10-, DK2620JI -N15, DK2620JI -N20-, DK2620JI -N25-, DK2620JI -N30-, DK2620JI -B15-, DK2620JI -B20-, DK2620JI -B25-, DK2620JI -B30-, DK2623JI -N15-, DK2623JI -N20-, DK2623JI -B15-, DK2623JI -B20-
510(k) number	K171096	To be assigned
Product code	KGE	KGE
Manufacturer	FUJIFILM Corporation	FUJIFILM Corporation
Intended Use	This instrument is designed to be used with specified endoscopes to cut tissue within the digestive tract and using high-frequency current. Both of the ball tip type and the needle type instruments are indicated for ablation, incision, dissection, avulsion, cauterization, coagulation and hemostasis of tissue within the digestive tract.	These products are used in combination with an applicable endoscope to perform the endoscopic treatments for the target site in the gastrointestinal tract, such as ablation, incision, dissection, cauterization, coagulation and avulsion of tissue and arrest of bleeding, and to inject saline or submucosal injection agent for endoscopic surgery into the submucosal layer in the gastrointestinal tract, which is exposed after dissection, under the management of physicians in medical facilities.
Slitter Length	1.0/1.5/2.0/2.5/3.0mm (for DK2618J series) 1.5/2.0mm (for DK2623J series)	Same as K171096
Slitter Diameter	0.5mm	Same as K171096
Slitter Shape	Needle Type (With Ball Tip:-BXX-) (Without Ball Tip:-NXX-)	Same as K171096
Maximum Diameter of Insertion Portion	2.7mm	Same as K171096
Water Feed Function	Yes	Same as K171096
Method of Operation	Manually (handle slider)	Same as K171096
Water supply connector	Yes, fixed	Yes, rotatable
Energy	Energy delivered from an electrosurgical generator	Same as K171096

Monopolar / Bipolar	Monopolar	Same as K171096
Sterilization	Yes (Single Use Device)	Same as K171096
Combination Tools	Endoscope, Electrosurgical generator, A Cord, Water supply unit	Endoscope, Electrosurgical generator, A Cord
Injection agent	Saline and other sterile liquids	Saline, Eleview (K150852), ORISE Gel(K180068)

Performance Data:

Electrical safety and electromagnetic compatibility of the proposed device was evaluated using the following standards: ANSI/AAMI ES60601-1:2005/(R)2012, IEC 60601-1-2:2014, IEC 60601-1-6:2013, IEC 60601-2-2:2017, and IEC 60601-2-18:2009.

Biocompatibility of the proposed device was evaluated using the following consensus standards: ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-10:2010, and ISO 10993-11:2017. 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.

Sterility of the proposed device was evaluated according to ISO 11135:2014 and the FDA guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile".

Device specific testing was conducted using the following consensus standard: ISO 8600-1:2015. Bench testing was conducted to validate the compatibility of subject device with submucosal injection agent.

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

- Maximum diameter of insertion portion
- Working length
- Slitter length
- Conductivity
- Liquid delivery amount

In all cases, the device met the pre-defined acceptance criteria for the test.

Conclusions:

The subject device shares the same intended use and similar indications as the predicate device (K171096).

Bench testing demonstrates that the subject device is as safe and effective as the predicate device. Thus, subject device is substantially equivalent to the predicate device.