DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 9, 2017

FUJIFILM Medical Systems U.S.A., Inc.
Jeffrey Wan
Specialist, Regulatory Affairs
10 High Point Drive
Wayne, NJ 07470

Re: K171096
Trade/Device Name: Fujifilm Diathermic Slitter (FlushKnife)
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: KGE
Dated: April 11, 2017
Received: April 13, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K171096

Device Name

Fujifilm Diathermic Slitter (FlushKnife)

Indications for Use *(Describe)*

Diathermic Slitter (FlushKnife) DK2618J and DK2623J are intended to be used with specified endoscopes to cut tissue using high-frequency current within the digestive tract. The devices are indicated for ablation, incision, dissection, avulsion, cauterization, coagulation and hemostasis of tissue within the digestive tract.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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XV. 510(K) SUMMARY

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.
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Date Prepared: May 8, 2017

Identification of the Proposed Device:

Proprietary/Trade Name:	Fujifilm Diathermic Slitter (FlushKnife)
Common Name:	Electrosurgical Instruments
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Classification Information:

Endoscopic electrosurgical unit and accessories 21 C.F.R. § 876.4300
Product Code: KGE

Predicate Device:

Fujifilm Diathermic Slitter (FlushKnife) and Diathermic Slitter (ClutchCutter) (K161186)

Purpose of the Special 510(k) notice:

The Diathermic Slitter (FlushKnife) is a modification to Diathermic Slitter (FlushKnife) (K161186).

Intended Use:

Diathermic Slitter (FlushKnife) DK2618J and DK2623J are intended to be used with specified endoscopes to cut tissue using high-frequency current within the digestive tract. The devices are indicated for ablation, incision, dissection, avulsion, cauterization, coagulation and hemostasis of tissue within the digestive tract.

Device Description:

Diathermic Slitter (FlushKnife) is sterile and intended for single used electrosurgical instruments that remove tissue and control bleeding by use of high-frequency ("HF") electrical current.

The device is comprised of a proximal handle with slider that is connected to a flexible resin tube. The flexible resin tube covers and insulates the operation wire and slitter (when retracted). The

operation wire controls the mechanical function of and delivers high frequency (HF) electrical current to the slitter. The proximal end of the operation wire is connected to the slider, which allows the operator to manually control the extension and retraction of the slitter. The distal end of the operation wire connects to the slitter, which is located at the distal tip of the device.

The device connects to a HF electrosurgical power supply unit by an active cord ("A-Cord") connector. HF electrical current generated by a HF electrosurgical power supply unit flows to the slitter from the HF electrosurgical power supply unit via the A-cord, the A-cord connector, and the operation wire.

The distal tip of the device is inserted through the forceps channel of the specified endoscope. Once inserted, the operator can extend the slitter from the tip of the endoscope using the slider. The slitter is extended to the target site of a patient. Cleavage, resection, incision, ablation, hemostasis, coagulation, or excision of tissue is achieved by delivering HF current to the target tissue through the slitter.

The device is provided sterile for single-use only.

The device can supply sterile water or fluids to its distal end target site via a water/fluid supply channel. The port for the water/fluid supply channel is located on the handle at the proximal end of the device. The sterile water or fluid also aids in the removal of debris, blood and extraneous material from the distal end of the device or a target site.

To supply sterile water or fluid to the distal end target site, a syringe filled with water or fluid is connected to the water/fluid inlet at the proximal handle.

Besides a syringe, alternate delivery methods can also be used to supply sterile water or fluid to the distal end target site of the device.

Technological Characteristics:
A table comparing the technological characteristics between FlushKnife and the predicate devices is shown below.

Summary of differences between modified FlushKnife from its predicate device

	Predicate Device	**Proposed Device**
Device Name	Fujifilm Diathermic Slitter (FlushKnife)	Fujifilm Diathermic Slitter (FlushKnife)
Device Models	DIATHERMIC SLITTER, 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-	Same as predicate device
510(k) Number	K161186	Pending

Intended Use		These instruments have been designed to be used with specified endoscopes to cut tissue using high-frequency current within the digestive tract. Both 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.	Same as predicate device
Technological Characteristics	Slitter Length	1.0/1.5/2.0/2.5/3.0mm (for DK2618 series) 1.5/2.0mm (for DK2623 series)	Same as predicate device
	Slitter Diameter	0.5mm	Same as predicate device
	Slitter Shape	Needle Type (With Ball Tip:-BXX-) (Without Ball Tip:-NXX-)	Same as predicate device
	Maximum Diameter of Insertion Portion	2.7mm	Same as predicate device
	Working Length	1800mm/2300mm	Same as predicate device
	Method of Operation	Manually (handle slider)	Same as predicate device
Energy used or delivered		energy delivered from a electrosurgical generator	Same as predicate device
Monopolar/Bipolar		Monopolar	Same as predicate device
Sterilization		Yes (Single Use Device)	Same as predicate device
Combination equipment		Endoscope Electrosurgical generator A Cord Syringe	Endoscope Electrosurgical generator A Cord Syringe Pump
Compatible fluids		Sterile water	Sterile water and other sterile fluids
Material of Insertion Portion		Stainless steel Ceramics Fluorine resin Fluorine coating Silver brazing filler metal	Same as predicate device

Performance Data

Fujifilm conducted the following performance testing on the proposed device FlushKnife to ensure that the modified device performs equivalently to the predicate device:

- Fluid supply
- Temperature rise
- Dielectric voltage
- Durability

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

Substantial Equivalence

The company's FlushKnife has the same intended use as the previously cleared predicate FlushKnife (K161186). In addition, the proposed device FlushKnife has the same intended use, indications for use, technological characteristics, and principles of operation as its predicate. Although there is a minor difference between the proposed device and its predicate device, namely the addition of compatible sterile fluids and alternate delivery systems, this difference does not raise new or additional questions of safety or effectiveness of the proposed device. Thus, the proposed device FlushKnife is substantially equivalent to its predicate device.