DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 29, 2016

Fujifilm Medical Systems USA, Inc.
Shraddha More
Specialist, Regulatory Affairs and Quality Assurance
10 High Point Drive
Wayne, NJ 07470

Re: K161186
Trade/Device Name: Fujifilm Diathermic Slitter (flushknife), Fujifilm Diathermic Slitter (clutchcutter)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: KGE
Dated: June 16, 2016
Received: June 17, 2016

Dear Shraddha More,

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 yours,

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)*

K161186

Device Name

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

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.

Diathermic Slitter (ClutchCutter) DP2618DT is intended to be used with specified endoscopes to cut tissue using high-frequency current within the digestive tract. The device is 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)*

XII. 510(K)

SUMMARY Submitter's

Information

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Inc. Endoscopy Division
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Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

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Date Prepared: April 26, 2016

Identification of the Proposed device:

Proprietary/Trade Name:	Fujifilm Diathermic Slitter (FlushKnife) and Diathermic Slitter (ClutchCutter)
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) (K151474)

Purpose of the Special 510(k) notice:

The Diathermic Slitter (FlushKnife) and Diathermic Slitter (ClutchCutter) is a modification to Diathermic Slitter (FlushKnife) and Diathermic Slitter (ClutchCutter) (K151474).

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.

Diathermic Slitter (ClutchCutter) DP2618DT is intended to be used with specified endoscopes to cut tissue using high-frequency current within the digestive tract. The device is indicated for ablation, incision, dissection, avulsion, cauterization, coagulation and hemostasis of tissue within the digestive tract.

Technological Characteristics:

Tables comparing the technological characteristics between FlushKnife and ClutchCutter and their respective predicate devices are 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		K151474	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 Shape	Needle Type (With Ball Tip:-BXX-) (Without Ball Tip:-NXX-)	Same as predicate device
	Maximum Diameter of Insertion Portion	φ2.7	Same as predicate device
	Working Length	1800mm/2300mm	Same as predicate device
	Water Feed Function	Yes	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
Biocompatibility		Yes	Same as predicate device
Accessories		None	Same as predicate device
Combination equipment		Endoscope, Electrosurgical generator, A Cord	Same as predicate device

Summary of differences between modified ClutchCutter from its predicate device

	Predicate device	Proposed Device
Device Name	Fujifilm Diathermic Slitter (ClutchCutter)	Fujifilm Diathermic Slitter (ClutchCutter)
Device Models	DP2618DT -35-, DP2618DT -50-	Same as predicate device
510(k) Number	K151474	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. These 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 Shape	Forceps Type	Same as predicate device
	Maximum Diameter of Insertion Portion	φ2.7	Same as predicate device
	Working Length	1800mm	Same as predicate device
	Slitter Portion Rotation Function	Yes	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
Biocompatibility		Yes	Same as predicate device
Accessories		None	Same as predicate device
Combination equipment		Endoscope, Electrosurgical generator, A Cord	Same as predicate device

Performance Data

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

FlushKnife

- Airtightness
- Maximum diameter of insertion portion
- Working length
- Slitter Portion length
- Electrical resistance

ClutchCutter

- Working length:
- Maximum diameter of insertion portion
- Distal end shapes
- Electrical resistance

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

Substantial Equivalence

The company's proposed device, FlushKnife and ClutchCutter have the same intended use as the previously cleared predicate FlushKnife and ClutchCutter (K151474). In addition, the proposed device, FlushKnife and ClutchCutter has same indications, technological characteristics, and principles of operation as its predicate. Although there are minor differences between the proposed device and its predicate device, namely modification in material (epoxy resin), those differences do not raise new questions of safety or efficacy. The minor change done in the material would not raise any new or additional questions in of safety or effectiveness of the proposed device. Thus, the proposed device, FlushKnife and ClutchCutter, is substantially equivalent to its predicate device.