



Food and Drug Administration  
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February 18, 2016

Fujifilm Medical System U.S.A., Inc.  
Mary Moore  
Senior Director, Regulatory Affairs and Quality Assurance  
10 High Point Drive  
Wayne, NJ 07470

Re: K151474  
Trade/Device Name: Fujifilm Diathermic Slitter (FlushKnife), Diathermic Slitter  
(ClutchCutter)  
Regulation Number: 21 CFR 876.4300  
Regulation Name: Endoscopic Electrosurgical Unit and Accessories  
Regulatory Class: Class II  
Product Code: KGE  
Dated: January 8, 2016  
Received: January 8, 2016

Dear Mary Moore,

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,

  
**Herbert P. Lerner -S**

for 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

## Indications for Use

510(k) Number (if known)

K151474

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**510(k) SUMMARY****FUJIFILM Medical Systems U.S.A., Inc.'s**

Diathermic Slitter (FlushKnife) and Diathermic Slitter (ClutchCutter)

**Date Prepared:** June 1, 2015**Sponsor's Information:**

FUJIFILM Medical Systems U.S.A., Inc.  
 Endoscopy Division  
 10 High Point Drive  
 Wayne, NJ 07470

**Contact Person:**

Mary K. Moore  
 Senior Director, Regulatory Affairs and Quality Assurance  
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 E-Mail: mkmoore@fujifilm.com

**Name of Device**

Proprietary Name: Fujifilm Diathermic Slitter (FlushKnife) and Diathermic Slitter (ClutchCutter)  
 Common or Usual Name: Electrosurgical Instruments  
 Device Class: Class II  
 Review Panel: Gastroenterology and urology

**Classification Information:**

Endoscopic Electrosurgical Unit and Accessories; 21 C.F.R. § 876.4300  
 Product Code: KGE

**Predicate Devices**

<b>510(K) Number</b>	<b>Device Trade Name</b>	<b>Manufacturer</b>
K062517	Electrosurgical Hemostatic Forceps Series	Olympus Medical Systems Corporation
K092309	Single Use Electrosurgical Knife Series, Model KD-610L, KD611L, KD620LR, KD630L, KF640L	Olympus Medical Systems Corporation

## Intended Use / Indications for 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.

## Device Description

The Fujifilm Diathermic Slitter (FlushKnife) and Diathermic Slitter (ClutchCutter) (the “devices”) are electrosurgical instruments that remove tissue and control bleeding by use of high-frequency (“HF”) electrical current. The devices are provided sterile for single-use only. The devices are provided in various models (described below), but each is comprised of the following major components:

The FlushKnife and ClutchCutter consist of the following major components:

- Slitter – Electrode at distal tip of the device that performs ablation, incision, dissection, avulsion, cauterization, coagulation, and hemostasis of tissue via delivery of HF electrical current.
- Operation wire – Inner wire of the device that connects the handle and slider control to the slitter, facilitates manual control of slitter position, and delivers the HF electrical current to the slitter.
- Tube – Flexible resin tube that is inserted into body cavities and insulates operation wire carrying the HF electrical current.
- Slider – Portion of handle that extends and retracts the slitter portion from the distal end of the tube (FlushKnife) or opens and closes slitter jaws (ClutchCutter) by means of the operation wire.
- Handle – Proximal end of the device that provides for user control.
- Active Cord (“A-Cord”) Connector – Used to connect the device to the electrosurgical power supply unit via an A-cord.

The devices are 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 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 (for the FlushKnife) or open and close (ClutchCutter) of the slitter Jaws. The distal end of the operation wire connects to the slitter, which is located at the distal tip of the device.

The devices connect to a HF electrosurgical power supply unit by an active cord (“A-Cord”) connector. HF electrical current generated by 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 (FlushKnife) or opens and closes slitter jaws (ClutchCutter) 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.

**Technological Characteristics**

A table comparing the technological characteristics between FlushKnife and ClutchCutter and their Predicate Devices is shown below.

Device Description	OLYMPUS MEDICAL SYSTEMS CORPORATION Single Use Electrosurgical Knife Series, (K092309 Predicate Device)	OLYMPUS MEDICAL SYSTEMS CORPORATION Electrosurgical Hemostatic Forceps Series, (K062517 Predicate Device)	FUJIFILM Medical Systems U.S.A., Inc., FlushKnife and ClutchCutter (Subject Device)	
			FlushKnife	ClutchCutter
<b>Intended Use / Indications for Use</b>	This instrument has been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue within the digestive tract and using high-frequency current.	This instrument has been designed to be used with Olympus endoscopes to cauterize, coagulate and perform hemostasis using high-frequency current within the digestive tract.	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.
<b>Models</b>	Model KD-610L, KD-620LR	Model FD-410LR	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 DP2618DT-35-, DP2618DT -50-

Device Description	OLYMPUS MEDICAL SYSTEMS CORPORATION Single Use Electrosurgical Knife Series, (K092309 Predicate Device)	OLYMPUS MEDICAL SYSTEMS CORPORATION Electrosurgical Hemostatic Forceps Series, (K062517 Predicate Device)	FUJIFILM Medical Systems U.S.A., Inc., FlushKnife and ClutchCutter (Subject Device)	
			FlushKnife	ClutchCutter
<b>Technological Characteristics</b>				
Slitter Shape	Needle Type with Ball Tip (KD-610L), Needle Type with hook portion (KD-620LR)	Forceps type	Needle Type (With Ball Tip:-BXX-) (Without Ball Tip:-NXX-)	Forceps type
Slitter Length	4.0 mm (KD-610L), 4.5 mm (KD-620LR)	Not Applicable	1.0/1.5/2.0/2.5/3.0mm (for DK2618 series) 1.5/2.0mm (for DK2623 series)	Not Applicable
Maximum Diameter of Insertion Portion	φ2.6	φ2.75	φ2.7	φ2.7
Working Length	1650mm	1650 mm	1800mm/2300mm	1800 mm
Water Feed Function	None	Not Applicable	Yes	Not Applicable
Method of Operation	Manually (handle slider)	Manually (handle slider)	Manually (handle slider)	Manually (handle slider)
Energy	energy delivered from an electrosurgical generator	energy delivered from an electrosurgical generator	energy delivered from an electrosurgical generator	energy delivered from an electrosurgical generator
Monopolar / Bipolar	Monopolar	Monopolar	Monopolar	Monopolar
Sterilization	Yes (Single Use Device)	Yes (Single Use Device)	Yes (Single Use Device)	Yes (Single Use Device)
Combination Tools	Endoscope, Electrosurgical generator, A Cord	Endoscope, Electrosurgical generator, A Cord	Endoscope, Electrosurgical generator, A Cord	Endoscope, Electrosurgical generator, A Cord

### Performance Data

EMC and electrical safety of the subject devices were evaluated using the following consensus standards: ANSI/AAMI ES60601-1:2005; IEC 60601-1-2:2007; IEC 60601-2-2:2009, and IEC 60601-2-18:2009.

Biocompatibility of the subject devices was evaluated using the following consensus standards: ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-7:2008; ISO 10993-10:2010.

Sterilization of the subject devices were evaluated according to the following consensus standards: ISO 11135-1:2007 and ISO 10993-7:2008.

Testing specific to the subject devices was conducted per ISO 8600-1:2013.

Subject devices conformed to the following additional standards related to packaging and shelf life:

- ASTM 1980:2007
- ISO 11607-1:2006
- ISO 11607-2:2006

### **Substantial Equivalence**

The Fujifilm Diathermic Slitter (FlushKnife) and Diathermic Slitter (ClutchCutter) are as safe and effective as the Single Use Electrosurgical Knife (K092309) and the Electrosurgical Hemostatic Forceps Series (K062517). The FlushKnife and ClutchCutter have the same intended uses and similar indications, technological characteristics, and principles of operation as their predicate devices. The minor technological differences between the FlushKnife and ClutchCutter and their predicate devices raise no new issues of safety or new concerns of effectiveness. Performance data demonstrate that the FlushKnife and ClutchCutter are as safe and effective as the Single Use Electrosurgical Knife and the Electrosurgical Hemostatic Forceps Series. Thus, the FlushKnife and ClutchCutter have substantially equivalent performance to their predicate devices.

### **Conclusions**

The subject devices are substantially equivalent to the predicates based on intended use/indications for use and technological characteristics. The minor technological differences between the FlushKnife and ClutchCutter and their predicate devices raise no new questions of safety or new concerns of effectiveness. Bench testing data demonstrated that the FlushKnife and ClutchCutter have substantially equivalent performance to the predicates.