DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 15, 2017

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

Re: K162749
Trade/Device Name: FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Codes: FDS, FDF
Dated: May 2, 2017
Received: May 4, 2017

Dear Shraddha S. 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,

Charles Viviano -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

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 below.

510(k) Number *(if known)*
K162749

Device Name
FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR

Indications for Use *(Describe)*
The FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR are intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.

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 Medical Systems U.S.A., Inc.'s
FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR

Date: September 29, 2016

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.,
Endoscopy Division
10 High Point Drive
Wayne, NJ 07470 USA
FDA Establishment Registration Number: 2431293

Contact Person:

Shraddha More
Specialist, Regulatory Affairs and Quality Assurance
Telephone: (973) 686-2627
Facsimile: (973) 633-8818
E-Mail: smore@fujifilm.com

Identification of the Proposed Device:

Proprietary/Trade Name:	FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR
Common Name:	Hood
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Classification Information:

Classification Name	CFR Section	Product Codes
Gastroscope and Accessories (Flexible/Rigid)	21 CFR 876.1500	FDS
Colonoscope and Accessories (Flexible/Rigid)	21 CFR 876.1500	FDF

Predicate Devices

- Fujifilm Hood Model DH-17EN (K143556)

Intended Use / Indications for Use

The FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR are intended to be used in combination with compatible endoscopes to maintain the field of view during endscopic procedures such as mucosal resection.

Device Description

FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR are intended to be used in combination with compatible endoscopes to maintain the field of view during endscopic procedures such as mucosal resection.

The FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR are comprised of three main sections: an attaching portion, a distal portion, and a drain portion. The attaching portion is a wider diameter opening which is used to connect the hood to an applicable endoscope; a distal portion is the ending portion of the hood which tapers into narrower diameter opening, the drain slits on the distal portion form drain portion which prevent the fluids lodging on the surface of the endoscope.

The subject devices are used in combination with their respective applicable Fujifilm's endoscopes as shown in the table 7.1. All the applicable endoscopes marketed in USA are cleared under respective 510(k) notices.

Technological Characteristics

A comparison of the technological characteristics between the subject and predicate devices is provided in the table below.

Table 7.1: Comparison of FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR with their predicate device DH-17EN (K143556)

	Predicate Device model DH-17EN (K143556)	**Proposed Device model DH-28GR**	**Proposed Device model DH-29CR**	**Proposed Device model DH-30CR**
Intended Use	This hood is intended to be used in combination with the dedicated Endoscope to maintain the field of view during endoscopic procedures.	These hoods are intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.	These hoods are intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.	These hoods are intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.
Appearance				
Outer diameter	11.5mm	11.8mm	13.0mm	14.8mm
Maximum diameter of attaching endoscope	13.5mm	15.5mm	16.5mm	18.4mm
Total length	8.0mm	17.0mm	17.0mm	17.0mm
Distance from the tip	1.5mm	7.0mm	7.0mm	7.0mm
Diameter of attaching portion	9.5mm	10.4 – 11.3 mm	11.6 – 12.3 mm	13.4 – 14.2 mm
Inner diameter of distal end	8.5mm	8.0mm	8.0mm	8.0mm
Size and number of the drain	N/A	Square hole 5.0mm×1.25mm 2piece	Square hole 5.0mm×1.25mm 2piece	Square hole 5.0mm×1.25mm 2piece
Sterility	Not sterilized	Sterilized	Sterilized	Sterilized
Reuse or not re-use	Single use	Single use	Single use	Single use
Applicable endoscopes	EN-530T and EN-580T EN-450T5 EC-450BI5	EG-590WR EG-580RD [Note] EC-580RD/M [Note] EC-580RD/L [Note] EG-600ZW [Note]	EG-530CT EG-590ZW	EC-590WM [Note] EC-590ZW/M [Note] EC-590ZW/L EC-530WM3 [Note] EC-530WI3 [Note] EC-530WL3 [Note] EC-530DL ES-530WE EC-590WM4 [Note] EC-590WI4 [Note] EC-590WL4 [Note] EC-590ZW3/M [Note] EC-590ZW3/L [Note] EC-600WM [Note] EC-600WI [Note] EC-600WL EC-600WL v2 EC-600HL EC-600ZW/M [Note] EC-600ZW/L [Note]

[Note] Not available in USA.

The principle of operation and intended use of the FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR are identical to that of the predicate device FUJIFILM Hood Model DH-17EN (K143556). The modifications done to the subject device include changes in dimensions, material and sterility status. The subject hoods are slightly longer and larger than the predicate device. Also, subject devices are provided sterilized, while predicate device is supplied non-sterilized.

As detailed in the following sections of the 510(k) notice, these changes do not alter the intended use or fundamental technology of the subject devices neither affects their safety and effectiveness.

Performance Data

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

Sterilization was evaluated according to the following consensus standards: ISO 11135:2014 and ASTM F1980-07:2011.

Endoscope specific testing was conducted using the following consensus standards: ISO 8600-1:2015; and ISO 8600-4:2014.

Subject devices met performance specifications in the following additional testing:

- Outer diameter
- Maximum diameter of attaching endoscope
- Inner diameter of distal end
- Inner diameter of attaching portion
- Distance from the tip

Substantial Equivalence

FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR have substantially the same intended use and similar indications, technological characteristics, and principles of operation as their predicate device Fujifilm Hood Model DH-17EN (K143556). The minor dimensional differences between the FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR and their predicate device Fujifilm Hood Model DH-17EN were made for the purpose of overall product enhancement and general technological advancement, and raise no new issues of safety or effectiveness. The material changes in the subject device do not raise new concerns regarding biocompatibility as discussed in section XVII. Performance data demonstrated that the FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR have substantial equivalent performance to the predicate device Fujifilm Hood Model DH-17EN (K143556). The subject devices are provided sterile to the end users as opposed to the predicate device which is provided non-sterile. The subject devices are successfully validated for the sterilization process as well as residual EO and ECH concentrations, supporting their safety equivalent to the predicate device.

Conclusions

The subject devices, Hood Models DH-28GR, DH-29CR and DH-30CR are substantially equivalent to their predicate device Hood Model DH-17EN (K143556), based on intended use/indications for use and technological characteristics. The differences in the dimensions and material between the subject devices and its predicate device raise no new issues of safety or effectiveness. Bench testing data demonstrated that the subject devices have substantially equivalent performance to the predicate. Thus, the subject devices FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR are as substantially equivalent as their predicate Fujifilm Hood Model DH-17EN (K143556).