



September 1, 2023

Fujifilm Healthcare Americas Corporation  
Chaitrali Kulkarni  
Sr. Regulatory Affairs Specialist  
81 Hartwell Avenue  
Suite 300  
Lexington, Massachusetts 02421

Re: K232314

Trade/Device Name: Hood (DH-106STL, DH-116STL, DH-126STL, DH-096ST)  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: FDS, FDF  
Dated: August 2, 2023  
Received: August 2, 2023

Dear Chaitrali Kulkarni:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sivakami Venkatachalam -S

*for*

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

## Indications for Use

Submission Number (if known)

K232314

Device Name

Hood (DH-106STL, DH-116STL, DH-126STL, DH-096ST)

Indications for Use (Describe)

This hood is 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.**

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**510(k) SUMMARY**

**FUJIFILM Medical Systems U.S.A., Inc.'s  
FUJIFILM Hood Models DH-106STL, DH-116STL, DH-  
126STL, and DH-096ST**

**Date: August 31, 2023**

**Submitter's Information**

FUJIFILM Healthcare Americas Corporation  
81 Hartwell ave  
Lexington, MA 02421

**Contact Person:**

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**Identification of the Proposed Device:**

Proprietary/Trade Name: Fujifilm Hood Models DH-106STL, DH-116STL, DH-126STL, and DH-096ST  
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<br>876.1500 | FDS           |
| Colonoscope and Accessories (Flexible/Rigid) | 21 CFR<br>876.1500 | FDF           |

**Predicate Devices**

- Fujifilm Hood Model DH-28GR, DH-29CR, DH-30CR (K162749)

### **Intended Use / Indications for Use**

The FUJIFILM Hood Models DH-106STL, DH-116STL, DH-126STL, and DH-096ST are intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.

### **Device Description**

FUJIFILM Hood Models DH-106STL, DH-116STL, DH-126STL, and DH-096ST are intended to be used in combination with compatible endoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.




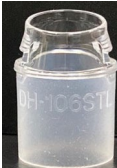



The FUJIFILM Hood Models DH-106STL, DH-116STL, DH-126STL, and DH-096ST are comprised of three main sections: an attaching portion, a distal portion, and a drain portion. The attaching portion is a wider diameter opening which is used to connect the hood to an applicable endoscope; a distal portion is 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 technological characteristics of FUJIFILM Hood Models DH-106STL, DH-116STL, DH-126STL, and DH-096ST with their predicate device DH-28GR, DH-29CR, DH-30CR (K162749)

|                                         | Predicate Device model<br>DH-28GR, DH-29CR, DH-30CR                               |                                                                                                                                                          |                                                                                   | Proposed Device model<br>DH-106STL, DH-116STL, DH-126STL                          |                                                                                                                                            |                                                                                     | Proposed Device model<br>DH-096ST                                                                                                                        | FUJIFILM Comments on Predicate Device model                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                         | DH-28GR                                                                           | DH-29CR                                                                                                                                                  | DH-30CR                                                                           | DH-106STL                                                                         | DH-116STL                                                                                                                                  | DH-126STL                                                                           | DH-096ST                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                         |
|                                         |  |                                                                         |  |  |                                                           |  |                                                                       |                                                                                                                                                                                                                                                                                                                                                                         |
| Manufacturer                            | DH-28GR<br>DH-29CR<br>DH-30CR<br>FUJIFILM corporation                             |                                                                                                                                                          |                                                                                   | DH-106STL<br>DH-116STL<br>DH-126STL<br>FUJIFILM corporation                       |                                                                                                                                            |                                                                                     | FUJIFILM corporation                                                                                                                                     | Same as Predicate Device model                                                                                                                                                                                                                                                                                                                                          |
| Outer diameter                          | DH-28GR                                                                           | 11.8mm                                                                                                                                                   |                                                                                   | DH-106STL                                                                         | 11.6mm                                                                                                                                     |                                                                                     | 11.0mm                                                                                                                                                   | The outer diameter changes slightly due to the shape change of the resin                                                                                                                                                                                                                                                                                                |
|                                         | DH-29CR                                                                           | 13.0mm                                                                                                                                                   |                                                                                   | DH-116STL                                                                         | 11.6mm                                                                                                                                     |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
|                                         | DH-30CR                                                                           | 14.8mm                                                                                                                                                   |                                                                                   | DH-126STL                                                                         | 13.7mm                                                                                                                                     |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
| Maximum diameter of attaching endoscope | DH-28GR                                                                           | 15.5mm                                                                                                                                                   |                                                                                   | DH-106STL                                                                         | 15.3mm                                                                                                                                     |                                                                                     | 14.2mm                                                                                                                                                   | DH-106STL, DH-116STL, DH-126STL<br>Since the dimensions of the rubber have been changed in line with the change in the shape of the resin, the maximum diameter will change when installed.<br><br>DH-096ST<br>Since the size of the rubber is reduced to combine with an endoscope that is thinner than the existing hood, the maximum diameter changes when attached. |
|                                         | DH-29CR                                                                           | 16.5mm                                                                                                                                                   |                                                                                   | DH-116STL                                                                         | 15.8mm                                                                                                                                     |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
|                                         | DH-30CR                                                                           | 18.4mm                                                                                                                                                   |                                                                                   | DH-126STL                                                                         | 16.8mm                                                                                                                                     |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
| Distance from the tip                   | DH-28GR                                                                           |                                                                                                                                                          |                                                                                   | DH-106STL                                                                         |                                                                                                                                            |                                                                                     | 6.0mm                                                                                                                                                    | In order to increase versatility, the protruding length was shortened to secure the field of view when the endoscope is attached.                                                                                                                                                                                                                                       |
|                                         | DH-29CR                                                                           | 7.0mm                                                                                                                                                    |                                                                                   | DH-116STL                                                                         | 6.0mm                                                                                                                                      |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
|                                         | DH-30CR                                                                           |                                                                                                                                                          |                                                                                   | DH-126STL                                                                         |                                                                                                                                            |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
| Total length                            | DH-28GR                                                                           |                                                                                                                                                          |                                                                                   | DH-106STL                                                                         |                                                                                                                                            |                                                                                     | 16.0mm                                                                                                                                                   | The total length is shortened by changing the Distance from the tip.                                                                                                                                                                                                                                                                                                    |
|                                         | DH-29CR                                                                           | 17.0mm                                                                                                                                                   |                                                                                   | DH-116STL                                                                         | 16.0mm                                                                                                                                     |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
|                                         | DH-30CR                                                                           |                                                                                                                                                          |                                                                                   | DH-126STL                                                                         |                                                                                                                                            |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
| Combination endoscope                   | DH-28GR                                                                           | EG-590WR, EG-580RD, EG-600ZW, EG-760Z, EC-580RD/M, EC-580RD/L, EC-740T/M, EC-740T/L                                                                      |                                                                                   | DH-106STL                                                                         | EG-760Z, EC-740T/L                                                                                                                         |                                                                                     | EG-760R                                                                                                                                                  | Appropriate endoscopes are set in combination according to the shape of the hood.                                                                                                                                                                                                                                                                                       |
|                                         | DH-29CR                                                                           | EG-760CT, EG-590ZW, EG-530CT, EC-760P-V/M, EC-760P-V/L                                                                                                   |                                                                                   | DH-116STL                                                                         | EG-760CT, EG-530CT, EC-760P-V/L                                                                                                            |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
|                                         | DH-30CR                                                                           | EC-760ZP-V/L, EC-600WL v2, EC-760R-V/L, EC-530DL, ES-530WE, EC-600HL, EC-760Z-V/L, EC-760S-V/L                                                           |                                                                                   | DH-126STL                                                                         | EC-600LS, EC-600WL, EC-760R-V/L, EC-760ZP-V/L                                                                                              |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
| How to attach to the endoscope          | DH-28GR                                                                           | Align the objective lens of endoscope with the drain of the hood and attach the hood to the distal end of endoscope by pressing the hood until it stops. |                                                                                   | DH-106STL                                                                         | Attach the hood to the distal end of the endoscope.                                                                                        |                                                                                     | Align the objective lens of endoscope with the drain of the hood and attach the hood to the distal end of endoscope by pressing the hood until it stops. | Same as Predicate Device model                                                                                                                                                                                                                                                                                                                                          |
|                                         | DH-29CR                                                                           |                                                                                                                                                          |                                                                                   | DH-116STL                                                                         | Align the opening of the distal portion of the hood with the instrument channel outlet of the endoscope and press the hood until it stops. |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
|                                         | DH-30CR                                                                           |                                                                                                                                                          |                                                                                   | DH-126STL                                                                         |                                                                                                                                            |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
| Existence of Sterile                    | DH-28GR                                                                           | EOG Sterilized                                                                                                                                           |                                                                                   | DH-106STL                                                                         | EOG Sterilized                                                                                                                             |                                                                                     | EOG Sterilized                                                                                                                                           | Same as Predicate Device model                                                                                                                                                                                                                                                                                                                                          |
|                                         | DH-29CR                                                                           |                                                                                                                                                          |                                                                                   | DH-116STL                                                                         |                                                                                                                                            |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
|                                         | DH-30CR                                                                           |                                                                                                                                                          |                                                                                   | DH-126STL                                                                         |                                                                                                                                            |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
| Reuse or not re-use                     | DH-28GR                                                                           | Single Use                                                                                                                                               |                                                                                   | DH-106STL                                                                         | Single Use                                                                                                                                 |                                                                                     | Single Use                                                                                                                                               | Same as Predicate Device model                                                                                                                                                                                                                                                                                                                                          |
|                                         | DH-29CR                                                                           |                                                                                                                                                          |                                                                                   | DH-116STL                                                                         |                                                                                                                                            |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |
|                                         | DH-30CR                                                                           |                                                                                                                                                          |                                                                                   | DH-126STL                                                                         |                                                                                                                                            |                                                                                     |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                         |

|                                   |         |                                                                                                                                                        |           |                                                                                                                                                        |                                                                                                                                                       |                                |
|-----------------------------------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Intended Use                      | DH-28GR | These hoods are intended to be used in combination with compatible endoscopes to maintain the field of view during observation of the digestive tract. | DH-106STL | These hoods are intended to be used in combination with compatible endoscopes to maintain the field of view during observation of the digestive tract. | These hoods are intended to be used in combination with compatible endoscopes to maintain the field of view during observation of the digestive tract | Same as Predicate Device model |
|                                   | DH-29CR |                                                                                                                                                        | DH-116STL |                                                                                                                                                        |                                                                                                                                                       |                                |
|                                   | DH-30CR |                                                                                                                                                        | DH-126STL |                                                                                                                                                        |                                                                                                                                                       |                                |
| Material                          | DH-28GR | Silicone rubber<br>Manufacturer: Shin-Etsu Chemical Co., Ltd. Model:KE-2090-60-A/B                                                                     | DH-106STL | Silicone rubber<br>Manufacturer: Shin-Etsu Chemical Co., Ltd. Model:KE-2090-60-A/B                                                                     | Silicone rubber<br>Manufacturer: Shin-Etsu Chemical Co., Ltd. Model:KE-2090-60-A/B                                                                    | Same as Predicate Device model |
|                                   | DH-29CR | Polycarbonate resin<br>Manufacture: Mitsubishi Engineering-Plastics Corporation Model: IUPILON S-2001R 5355                                            | DH-116STL | Polycarbonate resin<br>Manufacture: Mitsubishi Engineering-Plastics Corporation Model: IUPILON S-2001R 5355                                            |                                                                                                                                                       |                                |
|                                   | DH-30CR |                                                                                                                                                        | DH-126STL | Polycarbonate resin<br>Manufacture: Mitsubishi Engineering-Plastics Corporation Model: IUPILON S-2001R 5355                                            |                                                                                                                                                       |                                |
| Transport and Storage Environment | DH-28GR | Temperature: -20 to +60°C<br>Humidity: 10 to 95% (No condensation)<br>Atmosphere: 70 to 106 kPa(Within range of atmospheric pressure)                  | DH-106STL | Temperature: -20 to +60°C<br>Humidity: 10 to 95% (No condensation)<br>Atmosphere: 70 to 106 kPa(Within range of atmospheric pressure)                  | Temperature: -20 to +60°C<br>Humidity: 10 to 95% (No condensation)<br>Atmosphere: 70 to 106 kPa(Within range of atmospheric pressure)                 | Same as Predicate Device model |
|                                   | DH-29CR |                                                                                                                                                        | DH-116STL |                                                                                                                                                        |                                                                                                                                                       |                                |
|                                   | DH-30CR |                                                                                                                                                        | DH-126STL |                                                                                                                                                        |                                                                                                                                                       |                                |

The principle of operation and intended use of the FUJIFILM Hood Models DH-106STL, DH-116STL, DH-126STL, and DH-096ST are identical to that of the predicate device FUJIFILM Hood Model DH-28GR, DH-29CR, DH-30CR (K162749). The modifications done to the subject device include changes in dimensions and applicable endoscopes. The distance from the tip and total length is slightly smaller in the subject device compared to the predicate device. The maximum diameter of attaching endoscope of DH-096ST and DH-126STL is slightly smaller the predicate device.

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**

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
- Distance from the tip



## **Substantial Equivalence**

FUJIFILM Hood Models DH-106STL, DH-116STL, DH-126STL, and DH-096ST have substantially the same intended use and similar indications, technological characteristics, and principles of operation as their predicate device Fujifilm Hood Model DH-28GR, DH-29CR and DH-30CR (K162749) . The minor dimensional differences between the FUJIFILM Hood Models DH-106STL, DH-116STL, DH-126STL, and DH-096ST and their predicate device Fujifilm Hood Model DH-28GR, DH-29CR and DH-30CR (K162749) were made for the purpose of overall product enhancement and general technological advancement, and raise no new issues of safety or effectiveness. Performance data demonstrated that the FUJIFILM Hood Models DH-106STL, DH-116STL, DH-126STL, and DH-096ST have substantial equivalent performance to the predicate device Fujifilm Hood Model DH-28GR, DH-29CR and DH-30CR (K162749) .

## **Conclusions**

The subject devices, Hood Models DH-106STL, DH-116STL, DH-126STL, and DH-096ST are substantially equivalent to their predicate device Hood Model DH-28GR, DH-29CR and DH-30CR (K162749) , based on intended use/indications for use and technological characteristics. The differences in the dimensions 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-106STL, DH-116STL, DH-126STL, and DH-096ST are as substantially equivalent as their predicate Fujifilm Hood Model DH-28GR, DH-29CR and DH-30CR (K162749) .