January 30, 2026

Shanghai SeeGen Photoelectric Technology Co., Ltd.
Wang Li
RA Supervisor
Building No.5, 4277 YinDu Road, Minhang District
Shanghai, 201108
China

Re: K252457
Trade/Device Name: Disposable Distal End Tape Hood
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF
Dated: December 29, 2025
Received: December 29, 2025

Dear Wang Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

SHANIL P. HAUGEN -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252457

Device Name
Disposable Distal End Tape Hood

Indications for Use *(Describe)*
This product is intended to be used in combination with compatible colonoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.

This product needs to be cut and connected to the endoscope tip of φ9mm to φ14mm, and medical tape needs to be prepared in advance to fix it into a cylindrical shape.

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.

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

5.1Submitter

Submitted by:	Shanghai SeeGen Photoelectric Technology Co., Ltd. Address: Building No.5, 4277 YinDu Road, Minhang District, 201108 Shanghai, PEOPLE'S REPUBLIC OF CHINA
Contact Person:	Li Wang RA Supervisor
	Shanghai SeeGen Photoelectric Technology Co., Ltd. Address: Building No.5, 4277 YinDu Road, Minhang District, 201108 Shanghai, PEOPLE'S REPUBLIC OF CHINA Phone: 0086-13761127996 Email: wangli@seegen.com.cn
Date Prepared:	Aug 4, 2025

5.2Device

Device Name:	Disposable Distal End Tape Hood
Common Name:	Endoscope and accessories
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Colonoscope and Accessories (Flexible/Rigid)
Product Code:	FDF

5.3Predicate Device

Device Name:	FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR
Common Name:	Endoscope and accessories
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Gastroscope and Accessories (Flexible/Rigid); Colonoscope and Accessories (Flexible/Rigid)
Product Code:	FDS,FDF

5.4Device Description

This product is intended to be attached to an endoscope.

The Disposable Distal End Tape Hood is installed at the tip of the endoscope to assist the endoscope in a clearer observation. It can push away the mucosa and keep a certain distance between the lens and the mucosa, thus maintaining the field of view.

5.5 Indication for Use:

This product is intended to be used in combination with compatible colonoscopes to maintain the field of view during endoscopic procedures such as mucosal resection.

This product needs to be cut and connected to the endoscope tip of φ9mm to φ14mm, and medical tape needs to be prepared in advance to fix it into a cylindrical shape.

5.6Substantial Equivalence and Technological Characteristics

Detailed comparison table

Item	Disposable Distal End Tape Hood(Proposed product) The following code: WDA-160-20-01/WDA-160-20-02/WDA-160-20-03/WDA-160-20-01B/WDA-160-20-02B/WDA-160-20-03B	FUJIFILM Hood (Predicate product),K162749 The following code: DH-28GR/DH-29CR/DH-30CR	Comment
Indication for Use	This product is intended to be used in combination with compatible colonoscopes to maintain the field of view during endoscopic procedures such as mucosal resection. This product needs to be cut and connected to the endoscope tip of φ9mm to φ14mm, and medical tape needs to be prepared in advance to fix it into a cylindrical shape.	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.	Same as Predicate Device，we only include colonoscopes for compatible in indication for use.
Appearance			Similar1
Outer diameter （mm）	9~16	DH-28GR：11.8 DH-29CR：13.0 DH-30CR：14.8	Similar2
Maximum diameter of attaching endoscope (mm)	≤18	DH-28GR：15.5 DH-29CR：16.5 DH-30CR：18.4	Similar3
Total length/width (mm)	20.0	17.0	Similar4
Distance from the tip (mm)	2~5	7.0	Similar5
Diameter of attaching portion (mm)	N/A	DH-28GR：10.4 - 11.3 DH-29CR：11.6 - 12.3	Different1

		DH-30CR：13.4 – 14.2	
Inner diameter of distal end (mm)	9~14	8.0	Similar6
Size and number of the drain (mm)	N/A	Square hole 5.0mm×1.25mm 2piece	Different2
Sterility	Sterilized	Sterilized	Same
Reuse or not re-use	Single use	Single use	Same
Applicable endoscopes	9mm~14mm	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]	Similar7

Substantial equivalence analysis

Similar 1-Appearance

For figure,

The proposed product is designed for a wrapping style, which cause the different appearance between proposed product and predicate product . Both devices are installed on the endoscope lens section to maintain visual field during endoscopic surgery.

The little different appearance between them caused by their different usage methods.

510(k) Summary

Similar 2-Outer diameter

The outer diameter of the predicate product is DH-28GR:11.8mm/ DH-29CR:13.0mm/ DH-30CR:14.8mm, while the outer diameter rang of proposed product is from 9 to 16 mm. The applicable specification of endoscope is different between predicate product and proposed product. This dimensional design is based on the specification of endoscope. We have submitted performance comparison test reports and reliability verification reports to demonstrate that the difference do not raise new questions of safety and effectiveness.

The different between opaque hood and transparent hood of our proposed product is only colour, we have tested both of them. The opaque hood share same safety and effectiveness with transparent hood.

Similar 3-Maximum diameter of attaching endoscope

Maximum diameter of attaching endoscope of predicate product is DH-28GR：15.5mm/ DH-29CR：16.5mm/ DH-30CR：18.4mm, Maximum diameter of attaching endoscope of our proposesd product is ≤18mm，The range of Maximum diameter of attaching endoscope for our proposed product is in the range of predicate product, our proposed products do not raise new questions of safety and effectiveness.

The different between opaque hood and transparent hood of our proposed product is only colour, we have tested both of them. The opaque hood share same safety and effectiveness with transparent hood.

Similar 4-Total length/width (mm

The total length/width of the predicate product is 17mm, while our proposed product is 20mm. This difference does not affect the firmness of installation. We submit performance comparison test report and reliability test report to prove that our proposed product is as safe and effective as the predicate.

The different between opaque hood and transparent hood of our proposed product is only colour, we have tested both of them. The opaque hood share same safety and effectiveness with transparent hood.

Similar 5-Distance from the tip (mm

The distance from the tip of predicate product is 7mm, while the distance from the tip of the our proposed product is 2-5mm. This difference does not affect the image quality. We submit the performance comparison test report and image test report to prove that our declared product is as safe and effective as the predicate.

The different between opaque hood and transparent hood of our proposed product is only colour, we have tested both of them. The opaque hood share same safety and effectiveness with transparent hood.

Different 1-Diameter of attaching portion (mm

Since the Tape Hood is strip-shaped, it is wrapped around the applicable endoscope, so the inner diameter of the attaching portion is the size of the endoscope. Therefore it is not applicable.

The different between opaque hood and transparent hood of our proposed product is only colour, we have tested both of them. The opaque hood share same safety and effectiveness with transparent hood.

Similar 6-Inner diameter of distal end（mm）

The inner diameter of distal end of predicate product is 8.0mm, while the inner diameter of distal end of proposed product is7~16mm， The applicable specification of endoscope is different between predicate product and proposed product. This dimensional design is based on the specification of endoscope. We have submitted performance comparison test reports and reliability verification reports to demonstrate that the difference do not raise new questions of safety and effectiveness.

The different between opaque hood and transparent hood of our proposed product is only colour, we have tested both of them. The opaque hood share

same safety and effectiveness with transparent hood.

Different 2-Size and number of the drain (mm

The predicate product has drain holes, but our proposed product does not have drain holes. We submit image test report to prove that the image quality of our proposed product is not affected after water injection without drain holes, our proposed product is as safe and effective as the predicate.

The different between opaque hood and transparent hood of our proposed product is only colour, we have tested both of them. The opaque hood share same safety and effectiveness with transparent hood.

Similar 7-Applicable endoscopes

The applicable specification of endoscope is different between predicate product and proposed product. We have submitted performance comparison test reports and reliability verification reports to demonstrate that the difference do not raise new questions of safety and effectiveness.

The different between opaque hood and transparent hood of our proposed product is only colour, we have tested both of them. The opaque hood share same safety and effectiveness with transparent hood.

3. RDT2511005 Soak test and Water flow impact test,Pull off Test Report

Substantial equivalence Summary

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.
It has been shown in this 510(k) submission that the differences between the Disposable Distal End Tape Hood and the predicate device do not raise any questions regarding its safety and effectiveness. Disposable Distal End Tape Hood as designed and manufactured is as safe and effective as the predicate device and therefore is determined to be substantially equivalent to the referenced predicate device.

5.7 Substantial Equivalence

FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR, K162749 are used as predicate device compared to proposed device Disposable Distal End Tape Hood manufactured by Shanghai SeeGen Photoelectric Technology Co., Ltd.

5.8 Non-clinical Performance Data

TheDisposable Distal End Tape Hood has been successfully tested for its functions and performance and mechanical characteristics.
The biocompatibility of the patient contact materials per ISO 10993. Additional validations were conducted for the sterilization process and EO residual.

5.9 Clinical Test Data

No Clinical Study is included in this submission.

5.10 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Section 5 510(k) Summary based on the information provided in this premarket notification, Shanghai SeeGen Photoelectric Technology Co., Ltd has demonstrated that proposed device Disposable Distal End Tape Hood is substantially equivalent to Shanghai SeeGen Photoelectric Technology Co., Ltd’s currently marketed FUJIFILM Hood Models DH-28GR, DH-29CR and DH-30CR, K162749.