April 8, 2025

Hangzhou Sightnovo Medical Technology Co., Ltd.
Eric Shi, QA&QC
101M, Building 7, No. 22, Xinyan Road, Yuhang Economic and
Technological Development Zone, Yuhang District, Hangzhou
Hangzhou City, 311100, China

Re: K243027
Trade/Device Name: Disposable Aqueous Humor Collector (SnovoDAHC I-50, SnovoDAHC II-50, SnovoDAHC II-50-27, SnovoDAHC II-100-27)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QLY, FMI
Dated: September 23, 2024
Received: March 24, 2025

Dear Eric Shi:

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,

Shruti N. Mistry -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
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)*
K243027

Device Name
Disposable Aqueous Humor Collector (SnovoDAHC I-50, SnovoDAHC II-50, SnovoDAHC II-50-27, SnovoDAHC II-100-27)

Indications for Use *(Describe)*
It is intended for use by health care professionals for puncture, drainage and fluid collection of the anterior chamber of the eye.
Its operation is manual. The Disposable Aqueous Humor Collector is single use only.
The Disposable Aqueous Humor Collector is suitable for ophthalmic use.

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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K243027 510(k) Summary

1. Submitter Information

Company Name: Hangzhou Sightnovo Medical Technology Co., Ltd.

Address: 101M, Building 7, No. 22, Xinyan Road, Yuhang Economic and Technological Development Zone, Yuhang District, Hangzhou City, Zhejiang Province, China.

Phone: +86-571-88776936

Contact Person (including title): Eric Shi (QA&QC Manager)

E-mail : Eric-shi@isosh.com

Date Prepared: April 8, 2025

2. Subject Device Information

Type of 510(k) submission: Traditional

Common Name: Ophthalmic Syringe; Needle, Hypodermic;Single Lumen

Trade Name: Disposable Aqueous Humor Collector (SnovoDAHC I-50, SnovoDAHC II-50, SnovoDAHC II-50-27, SnovoDAHC II-100-27)

Regulation Name: Piston syringe;

Hypodermic single lumen needle

Review Panel: General Hospital

Product Code: QLY;FMI

Regulation Number: 21 CFR 880.5860;21 CFR 880.5570

Regulation Class: 2

3. Predicate Device Information

K200242

Type of 510(k) submission: Traditional

Common Name: Ophthalmic Syringe; Syringe,Piston; Needle,Hypodermic,Single Lumen Trade Name: StaClear Syringe

Regulation Name: Piston syringe; Hypodermic single lumen needle

Review Panel: General Hospital

Product Code: QLY; FMF; FMI,

Regulation Number: 21 CFR 880.5860; 21 CFR 880.5570

Regulation Class: 2

4. Device Description

Model: SnovoDAHC I-50, SnovoDAHC II-50, SnovoDAHC II-50-27, SnovoDAHC II-100-27

Volume:50μL,100μL

Needle Gauge: 25G, 27G

The liquid collecting needle of this product is 25G,27G, the Needle point penetration force is ≤ 0.70N, and the liquid production volume and precision is 50 μL±20%, 100μL±20%, resistance to corrosion of the liquid collecting needle, total content of heavy metals not exceed 5μg/mL.

Disposable aqueous humor collector is composed of a liquid collecting needle sheath, a liquid collecting needle, a needle seat, a liquid collecting needle rubber sheath, a rubber plug, a liquid collecting tube, a cylinder body, a rubber ring, push rod and buckle structure.

5. Intended Use/Indications For Use

It is intended for use by health care professionals for puncture, drainage and fluid collection of the anterior chamber of the eye.

Its operation is manual. The Disposable Aqueous Humor Collector is single use only.

The Disposable Aqueous Humor Collector is suitable for ophthalmic use.

6. Summary of Comparison and Technological Characteristics

Table 1-General Comparison

Elements of Comparison	**Subject Device**	**Predicate Device**	**Comment**
Trade Name	Disposable Aqueous Humor Collector	StaClear Syringe	--
Common Name	Ophthalmic Syringe; Needle,Hypodermic; Single Lumen	Ophthalmic Syringe; Syringe,Piston; Needle,Hypodermic,Single Lumen	--
General Comparison			

Elements of Comparison	**Subject Device**	**Predicate Device**	**Comment**
510(k) Number	K243027	K200242	N/A
Regulation Name	Ophthalmic Syringe;Needle, Hypodermic,Single Lumen	Piston syringe; Hypodermic single lumen needle	Same
Regulation Number	21 CFR 880.5860; 21 CFR 880.5570	21 CFR 880.5860; 21 CFR 880.5570	Same
Product Code	QLY;FMI	QLY;FMF;FMI	Same
Indications For Use	It is intended for use by health care professionals for puncture, drainage and fluid collection of the anterior chamber of the eye. Its operation is manual. The Disposable Aqueous Humor Collector is single use only. The Disposable Aqueous Humor Collector is suitable for ophthalmic use.	The StaClear Syringe is intended to inject fluids into, or withdraw fluids from, the body. The StaClear Syringe is indicated for intravitreal use.	Note 1
Mechanism of Action	Manual	Manual	Same
Volume	50μL,100μL	0.25 mL(250μL)	Note 2
Single Use Only	YES	YES	Same
Sterilization Information	Provided Sterile, single-use Sterilization Method: Irradiation sterilization SAL: 10^{-6}	Provided Sterile, single-use Sterilization Method: Ethylene Oxide SAL: 10^{-6}	Note 3
Shelf Life	2 years	1 year	Note 4
Device Materials	1. liquid collecting needle sheath-MABS; 2. liquid collecting needle-ASTM 304 Stainless; 3. needle seat-Polypropylene; 4. liquid collecting needle rubber sheath-Natural rubber; 5. rubber plug-Butyl Rubber; 6. liquid collecting tube-polyethylene terephthalate; 7. cylinder body-High transparency MABS; 8. rubber ring-silica gel;	Barrel-Polypropylene Plunger-Polyethylene Plunger Stopper-Polyisoprene (Nipol IR2200, Zeon Chemicals) Needle-ASTM 304 Stainless Steel Needle Shield-Polyethylene Plunger Cap-Polyethylene Barrel Lubricant-Silicone Oil, crosslinked with inert argon gas plasma	Note 5

Elements of Comparison	Subject Device	Predicate Device	Comment
	push rod-Porcelain white ABS; buckle-ABS		
Connector Type	Attached needle	Attached needle	Same
Needle Gauge	25G,27G	31G	Note 2
Needle Length	5(+0.5,-1mm)	5/16 in (7.937mm)	Note 2
Biocompatibility Endpoint For Ophthalmic Use	Irritation, Ocular: Not considered irritants to the ocular tissue Irritation; Intracameral Injection: Not considered inflammatory to intraocular tissues	Irritation,Ocular: Not considered irritants to the ocular tissue Irritation Intravitreal Injection: Not considered inflammatory to intraocular tissues	Note 5
Performance test	Complied with ISO 7886-1, ISO 9626, ISO 7864	Complied with ISO 7886-1, ISO 9626, ISO 7864	Same
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801	Same

Note 1: The subject device, which is intended to withdraw fluids from the body, is appropriate for marketing under the regulations for piston syringe, 21 CFR 880.5860, and hypodermic single lumen needle, 21 CFR 880.5570.

However, after collecting aqueous humor from the eye, this device does not have the function of injection.

This difference in indications for use between the subject and predicate device does not raise new or different questions of safety and effectiveness.

Note 2: The volume of the subject device is smaller than that of the Predicate Device.

The parameters of the subject device's Needle Gauge and Needle Length are smaller than the Predicate Device. The technological characteristics of the subject device are substantially equivalent to the predicate device with differences in the device materials, syringe volume, needle gauge, and needle length. The differences in volume and needle gauge/length do not raise new or different questions of safety and effectiveness.

Note 3: The sterilization method of the subject device is different as the sterilization of the predicate device. However, they all have SAL of 10^{-6}. The difference in sterilization method does not raise new or different questions of safety and effectiveness.

Note 4: Sterilization and shelf life validation for this product confirms the 2 year shelf life.

Note 5: Material differences are addressed through biocompatibility testing per the ISO 10993 series.

7. Non-Clinical Tests Performed On The Proposed Device

The company has performed non-clinical performance testing based on its risk assessment utilizing Failure Mode Effect Analysis (FMEA).

Following Quality System processes, required testing was conducted to validate the cumulative modifications made to the subject devices.

Substantial Equivalence is being supported with full performance testing.

7.1 Bench Functional Performance

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device.

These tests include:

- ISO 7886-1:2017, Sterile hypodermic syringes for single use. Part 1: Syringes for manual use
- ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
- ISO 7864:2016, Sterile hypodermic needles for single use — Requirements and test methods

7.2 Clinical Testing

An outside of the United States (OUS) study was performed demonstrating the effectiveness of the subject device to collect 50 uL of liquid with the 50 uL model.

8. Biocompatibility Testing

The Disposable Aqueous Humor Collector is categorized as an externally communicating device with limited (≤24 hrs) tissue contact. Testing was conducted according to relevant sections of the ISO 10993 series.

Additionally,

USP <788> Particulate Matter in Injection.

USP <789> Particulate Matter in ophthalmic solutions

9. Reprocessing, Sterility and Shelf-Life

ISO 11137-2:2022 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

ANSI AAMI ST72:2019 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing

USP <85> Bacterial Endotoxin Determination

Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile - Guidance for Industry and Food and Drug Administration Staff

Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices - Guidance for Industry and Food and Drug Administration Staff

10. Conclusion

The technological characteristics of the subject device are substantially equivalent to the predicate device with differences in the indications for use, device materials, syringe volume, needle gauge, needle length. Biocompatibility testing and performance testing demonstrate these differences do not raise new or different questions of safety and effectiveness when compared to the predicate device. Based on the information provided within this 510(k) submission, the proposed subject device is substantially equivalent to the predicate device and is as safe and as effective as the legally marketed predicate device.