October 23, 2024

TSK Laboratory International Japan KK
Seika Shiba
Regulatory Affairs Specialist
2-1-5 Hirayanagi-Cho
Tochigi-Shi, Tochigi 328-0012
Japan

Re: K242073
Trade/Device Name: STERiJECT Ophthalmic Needle; STERiJECT Ophthalmic Needle Low Dead Space (LDS)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: QYM
Dated: September 23, 2024
Received: September 24, 2024

Dear Seika Shiba:

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)*
K242073

Device Name
STERiJECT Ophthalmic Needle; STERiJECT Ophthalmic Needle Low Dead Space (LDS)

Indications for Use *(Describe)*
The device is intended to inject into or aspirate from, the body.
The device is intended for intravitreal 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510 (k) Summary

Preparation Date: October 22nd, 2024

1. Contact Details

Applicant Name: TSK Laboratory International Japan KK
Applicant Address: 2-1-5 Hirayanagi-Cho Tochigi-Shi Tochigi-Ken 328-0012 Japan
Applicant Contact Telephone: 81 282 25 5200
Applicant Contact: Seika Shiba
Applicant Contact Email: shiba@tsklab.com

2. Device Name

Device Trade Name: STERiJECT Ophthalmic Needle;
STERiJECT Ophthalmic Needle Low Dead Space (LDS)
Device: Ophthalmic Needle
Classification Name: Ophthalmic Needle
Regulation Name: Hypodermic single lumen needle
Medical Specialty: General Hospital
Regulation Number: 21 CFR 880.5570
Product Code(s): QYM (Ophthalmic Needle)
Device Class: Class II

3. Legally Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
K230951	Terumo Injection Filter Needle	QYM

Reference #	Reference Device Trade Name	Product Code
K231734	STERiJECT Low Dead Space, STERiJECT The INViSIBLE Needle	QNS

4. Device Description Summary

The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a luer lock or luer slip piston syringe. The device can be used by health care professionals. The hub of the needle can be a standard size or a reduced size (low dead space) that is designed to reduce medication waste. The device is operated manually by attaching it to a piston syringe. Target injection sites include subcutaneous, intramuscular, intradermal, and intravitreal.

Models:

Model	Connector Type	Thread Type	Dead Space
LDS	Luer lock, Luer slip	Thread	Low
HPC	Luer lock, Luer slip	Thread	Standard
PRC	Luer lock, Luer slip	Lug	Standard

Product sizes and color codes of the label:

Nominal OD (mm)	Nominal Gauge Size Ref Std	Label Color	Length (mm)
Φ 0.18	ISO 34G	Orange	4, 6, 9
Φ 0.20	ISO 33G	Black	4, 6, 9, 13
Φ 0.23	ISO 32G	Deep Green	4, 6, 9, 13
Φ 0.24	ENE 33G	Black	4, 6, 9, 13
Φ 0.25	ISO 31G	White	4, 6, 9, 13
Φ 0.26	ENE 32G	Deep Green	4, 6, 9, 13
Φ 0.28	ENE 31G	White	4, 6, 9, 13
Φ 0.30	ISO 30G	Yellow	4, 6, 9, 13
Φ 0.33	ISO 29G	Red	4, 6, 9, 13
Φ 0.36	ISO 28G	Blue Green	4, 6, 9, 13
Φ 0.40	ISO 27G	Medium Grey	4, 6, 9, 13

5. Intended Use/Indication for Use

The device is intended to inject into or aspirate from, the body.
The device is indicated for intravitreal use.

6. Indications for Use Comparison

The subject device has completed testing to show that the device meets its intended use/indication for use and demonstrates substantial equivalence to the predicate device K230951.

7. Technological Comparison

The table below includes a comparison of the technological characteristics between the subject device and those of the predicate device and reference device:

Technological Characteristic	Subject Device	Predicate Device	Reference Device	Discussions
Trade name	STERiJECT ophthalmic Needle; STERiJECT Ophthalmic Needle Low Dead Space (LDS),	Terumo Injection Filter Needle (NF-3013RBKE05M) (K230951)	STERiJECT Low Dead Space (LDS); STERiJECT The INViSIBLE Needle (K231734)	
Indications for Use	The device is intended to inject into or aspirate from, the body. The device is indicated for intravitreal use.	The Terumo Injection Filter Needle is indicated for general application - for treatment - injection of fluids into parts of the body below the surface of the skin and into the vitreous.	To inject fluids into or aspirate from, the body.	Same
Regulation	880.5570	880.5570	880.5570	Same
Product Code	QYM	QYM	QNS	Same
Class	Class II	Class II	Class II	Same
Gauge	27G – 34G	30G	21G – 34G	Different. See Discussion #2
Length	4mm – 13mm	12mm (½")	4mm – 120mm	Different. See Discussion #2
Dead Volume **OPHTHALMIC NEEDLE** **OPHTHALMIC NEEDLE LDS**	 Standard 0.0028ml	 Unspecified	 0.0028ml	Different. See Discussion #4
Safety Feature	No safety feature	unspecified	No safety feature	See Discussion #1
Syringe compatibility	Luer Lock or Luer Slip	Unspecified	Luer Lock or Luer Slip	Same
Hub	Polycarbonate	PMMA/Masterbatch	Polycarbonate	Different. See Discussion #5
Needle tube	Stainless Steel	Stainless Steel	Stainless Steel	Same
Adhesive	Epoxy	Acrylic Glue	Epoxy	Different. See Discussion #5
Lubricant	Silicon oil	Silicone (Polydimethylsiloxane)	Silicone oil	Same
Sterilization method	Gamma irradiation	EO gas	Gamma irradiation	Different See Discussion #3

Discussions of differences in technological characteristics

Discussion #1
The subject device does not have a safety feature. In general, the safety feature is optional for hypodermic or ophthalmic needles and not having the safety feature does not raise new or different questions of safety and effectiveness when compared to the predicate device.

Discussion #2

The difference in specifications does not raise new questions of safety and effectiveness. The subject device was tested to the same standards as the predicate device K230951. The substantial equivalence of the device is confirmed through performance testing.

Discussion #3
The sterility of the subject device has been validated to achieve SAL of 10-6 in accordance with ISO 11137-1 and ISO 11137-2. Packaging integrity tests were conducted according to ISO 11607-1 and ASTM F3039 to ensure that the hard pack packaging serving as the sterile barrier system is maintained over the life of the device. K230951 is sterilized using EtO gas sterilization which uses standards ISO 11135 whereas the subject device uses gamma irradiation. K231734, which does use gamma irradiation, has been validated to achieve SAL of 10-6 in accordance with ISO 11137-1 and ISO 11137-2, therefore the difference between the subject and predicate device does not raise new or different questions of safety and effectiveness.

Discussion #4
The subject device has standard hubs or low dead space hubs. Standard hubs meet all the requirements for ISO 80369-7 which defines the connector requirements for standard needle hub connections. Low dead space hub meets the requirement for ISO 80369-7 with the exception of the needle hub depth. There are currently no recognized standards for low dead space needles, however the physical characteristic of the low dead space hub is identical to K231734. The difference between the subject and predicate device does not raise new or different questions of safety and effectiveness.

Discussion #5
Although the materials of the subject device are different the from predicate device K230951, the biocompatibility of the materials was tested and meets the biocompatibility requirements of the applicable standards in the ISO 10993 series. Shelf-life study was conducted, and the result demonstrates the subject device continues to meet its specifications for 5 years after gamma irradiation.

The substantial equivalence of the subject device has been demonstrated by non-clinical testing data, hence the differences between the subject device and the predicate do not raise any new or different questions of safety or effectiveness. Therefore, it is concluded that the subject device is substantially equivalent to the legally marketed predicate device K230951.

8. Non-clinical and/or Clinical Tests Summary & Conclusions

The subject device was tested and demonstrated to be in conformance with the following FDA recognized standards.

• 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
• ISO 80369-7: 2021 Small-bore connectors for liquid and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications.

The standard hub needle models meet the requirements for ISO 80369-7. The subject device meets the requirements for ISO 80369-7 with the exception of the needle hub length which creates the dead space for the low dead space needle models. There are currently no FDA recognized standards for low dead space needles, however, it is equivalent to K231734 which also has a low dead volume hub. The subject device's ability to meet the connection requirements of ISO 80369-7 confirms the device's ability to secure connection for the low dead space needles.

<u>Biocompatibility</u>

In accordance with ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", the needle is classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (<24 hours). For Ophthalmic biological effects the device is also evaluated for Ocular Irritation, Intravitreal Injection Irritation, and as per USP788/789 "Particulate Matter in Ophthalmic Solutions", and as per FDA Guidance "Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices" each lot is tested for 0.2 EU/Device.

The following testing was conducted:

- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

- ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- USP Chapter <151> , ISO 10993-11 Pyrogen Test

Sterility, Shipping and Shelf-Life

Sterilization validation was performed in accordance with standards listed below.

- ISO 11137-1:2006/AMD 1:2013 Sterilization of health care products-Radiation -Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2006 Sterilization of health care products-Radiation - Part 2: Establishing the sterilization dose

Packaging validation was performed in accordance with the standards listed below.

- ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ASTM F3039-15 Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration
- ASTM D4169 – 22 Standard Practice for Performance Testing of Shipping Containers and Systems

Shelf life of 5 years validated using the standard listed below.

- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

The result of non-clinical testing demonstrates the substantial equivalence of the subject device.

9. Conclusion

The differences between the predicate devices and the subject device do not raise any new or different questions of safety or effectiveness. The subject device is substantially equivalent to K230951.