March 8, 2024

TSK Laboratory International Japan KK
Kana Ebina
Quality Assurance/ Regulatory Affairs Manager
2-1-5 Hirayanagi-Cho
Tochigi-Shi, Tochigi-Ken 328-0012
Japan

Re: K231734
Trade/Device Name: STERiJECT Low Dead Space, STERiJECT The Invisible Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: QNS
Dated: February 4, 2024
Received: February 6, 2024

Dear Kana Ebina:

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.

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, MS
Assistant Director
Division of Drug Delivery and General
Hospital Devices, and Human Factors
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)*
K231734

Device Name
STERiJECT Low Dead Space;
STERiJECT The INViSIBLE Needle

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

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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K231734 510 (k) Summary

Preparation Date: March 8, 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: Mrs. Ebina Kana

Applicant Contact Email: kana@tsklab.com

2. Device Name

Device Trade Name: STERiJECT Low Dead Space, STERiJECT The INViSIBLE Needle

Regulation Name: Hypodermic Single Lumen Needle

Regulation Number: 21 CFR 880.5570

Product Code(s): QNS

Device Class: Class II

3. Legally Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
K210444	EZ-Injec LDV Sterile Safety Needle	QNS

Reference #	Reference Device Trade Name	Product Code
K970370	TSK STERIJEKT PREMIUM DISPOSABLE HYPODERMIC NEEDLE	FMI

4. Device Description Summary

A low dead space single lumen hypodermic needle is a device designed to reduce medication waste. 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 syringes. The devices are intended to be used by doctors, medical- related practitioners and self-injection

by patients as directed by doctors or medical-related practitioners.
The needle hub or connector of the needle is designed to reduce medication waste. Low dead space needles are operated manually by attaching it to a piston syringe. Target injection sites include subcutaneous, intramuscular, intravascular, and intradermal.

Nominal Gauge Size	Minimum Length	Maximum Length
34 G	4mm	9mm
31 – 33 G	4mm	13mm
26 – 30 G	4mm	38mm
22 – 25 G	4mm	100mm
21 G	19mm	120mm

5. Intended Use/Indication for Use

This device is intended to inject into or aspirate from, the body.

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 K210444 and K970370.

7. Technological Comparison

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

Technological Characteristic	Subject Device	Predicate Device	Reference Device	Comments
	STERiJECT Low Dead Space (LDS) STERiJECT The INViSIBLE Needle K231734	EZ-Injec LVD Sterile Safety Needle K210444	TSK STERIJEKT PREMIUM DISPOSABLE HYPODERMIC NEEDLE K970370	
Indications for Use	This device is intended to inject into or aspirate from, the body.	This product is intended for use to inject fluid into or withdraw	To inject fluids into, or withdraw fluids from parts of the body below	Same

		fluids from parts of the body below the surface of the skin.	the surface of the skin.	
Regulation	880.5570	880.5570	880.5570	Same
Product Code	QNS	QNS	FMI	Same
Class	Class II	Class II	Class II	Same
Gauge	21G – 34G	25G	14G – 31G	See comment #1
Length	4mm – 120mm	25mm	6mm – 89mm	See comment #1
Dead Volume	0.0028ml	≤0.0054ml	Unspecified	See comment #2
Safety Feature	No safety feature	Include safety feature	No safety feature	See comment #3
Hub	Polycarbonate	Polypropylene	Polypropylene	See Comment #4
Syringe compatibility	Luer Lock Luer Slip	Luer Lock Luer Slip	Luer Lock Luer Slip	Same
Protector	Plastic	Plastic	Plastic	Same
Cannula	SUS304	SUS304	SUS304	Same
Adhesive	Epoxy	Epoxy	Epoxy	Same
Sterilization method	Gamma irradiation	EO gas	Gamma irradiation	See comment #5

Discussions of differences in technological characteristics

Comment #1

The additional gauges and needle length allow physician choice. The gauges and lengths meet appropriate recognized standards therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.

Comment #2

The subject device has a reduced hub size resulting in a lower dead space. The design of the subject device has been validated in accordance with the FDA recognized consensus standards therefore it does not raise new questions of safety and effectiveness for the subject device when compared to the predicate device.

Comment #3

The safety feature is optional for injection needles and not having the safety feature is still considered safe to use therefore it does not impact the safety and effectiveness of the subject device when compared to the predicate device.

Comment #4
Material was tested and meets the biocompatibility requirements. The subject device has been validated in accordance with the FDA recognized consensus standards therefore it does not raise new questions of safety and effectiveness of the subject device when compared to the predicate device.

Comment #5

The subject device and K970370 are sterilized using gamma irradiation and the K210444 device is sterilized using EO gas. The subject device has been validated in accordance with the FDA recognized standards therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.

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 devices, K210444 and K970370.

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 subject device meets the requirements for ISO 80369-7 with the exception of the needle hub length which creates the dead space. There are no currently FDA recognized standards for low dead space needles, however, it is similar to K210444 which also has a low dead volume hub. The subject device's ability to meet the connection requirements of ISO 80369-7 eliminates the risk of poor connection as the reduced hub length on the low dead space needles.

Additionally, bench testing demonstrating the low dead space capability of the needle was conducted.

<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). The following testing was conducted:

- ISO 10993-5:2009 Biological evaluation of medical devices Part 11: 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
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- USP Chapter <151> Pyrogen Test
- Particulate matter testing was conducted in accordance with USP <789> Particulate Matter in Ophthalmic Solutions and met the USP acceptance criteria.

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 11137-2:2013 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 the K210444 and K970370 with respect to indications for use, target population and technological characteristics.