July 30, 2025

TSK Laboratory, Japan
℅ Anna Galea
Principal Strategy Consultant
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, Minnesota 55426

Re: K250127
Trade/Device Name: TSK Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QNQ, FMF
Dated: June 23, 2025
Received: June 27, 2025

Dear Anna Galea:

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,

Kyran R. Gibson -S

For

Shruti Mistry
Assistant Director, Injection Devices
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)*
K250127

Device Name
TSK Syringe

Indications for Use *(Describe)*

The TSK Syringe is a low dead volume syringe intended for use in patients that need injection and withdrawal of substances for examination, treatment, diagnosis or prevention.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K250127 510(k) Summary

TSK Syringe

Submitter:

TSK Laboratory, Japan
1510-1, Soja-Machi, Tochigi-Shi Tochigi-Ken 328-0002 Japan
+81-282-25-7575
Ms Yumi Ueda
y.ueda@tsklab.co.jp

Date Prepared: July 30, 2025

Correspondent:

NAMSA
400 Highway 169 South, Suite 500, Minneapolis, MN 55426 United States
+1 339-927-2945
Dr. Anna Galea
agalea@namsa.com

Device Name:	TSK Syringe
Device Trade Name:	TSK Syringe
Common Name:	Piston Syringe
Classification Name:	Low Dead Space Piston Syringe, Piston Syringe
Regulation Number:	880.5860
Product Codes:	QNQ, FMF
Regulation Class:	II
Predicate:	PLPT LDV (Low Dead Volume) Sterile Syringe (K210443), Product Code QNQ

Device Description Summary:

The TSK Syringe is a syringe intended for use with a needle to inject or withdraw substances, for general use. The TSK Syringe leaves a low volume of fluid when the plunger is fully depressed.

There are two model numbers for the TSK Syringe. The technological differences are as follows:

Number	Syringe Nominal Capacity (mL)

TSY-0071P	0.7
TSY-0101Y	1.0

Indications for Use:

The TSK Syringe is a low dead volume syringe intended for use in patients that need injection and withdrawal of substances for examination, treatment, diagnosis or prevention.

Indications for Use Comparison:

The indication for use is the equivalent to the predicate device with minor differences in wording.

Technological Comparison:

The components and principle of operation are the same as the predicate. Device materials are similar with slight differences that do not impact safety or effectiveness, evaluated through testing. Syringe sizes are similar. The subject device also comes in a size smaller than 1 mL, which is not uncommon for other syringes in this classification. All features are documented in the table below.

Comparison of Subject Device to Predicate Device	**Subject Device TSK Syringe**	**Predicate Device PLPT LDV (Low Dead Volume) Sterile Syringe (K210443)**	**Comparison**
Manufacturer	TSK Japan	Poonglim Pharmatech Inc.	N/A
Regulation	21 CFR 880.5860	21 CFR 880.5860	Same
Product Code	QNQ FMF	QNQ	Same
Class	II	II	Same
Regulation Description	Piston syringe	Piston syringe	Same
Indications for Use	The TSK Syringe is a low dead volume syringe intended for use in patients that need injection and withdrawal of substances for examination, treatment, diagnosis or prevention.	PLPT LDV (Low Dead Volume) Sterile Syringe is intended to be used for medical purpose to inject fluid into or withdraw fluid from body.	Same
Intended Use	The TSK Syringe is a general purpose syringe intended for use with a needle to inject or withdraw substances.	It is intended for various medical applications and is not dedicated to medication administration.	Same
Intended User and Environment	The TSK Syringe is intended for use by healthcare professionals	Healthcare professionals	Same
Principal of Operation/Mechanism of Action	For manual use with a needle for injection or withdrawal of fluids.	A calibrated barrel (cylinder) with plunger intended to be used for	Same

		injection/withdrawal of fluids/gas (e.g., medication) to/from a medical device or the body (i.e., capable of both); a needle is not included	
Device Components	Piston syringe consisting of barrel, gasket, plunger, and lubricant	Piston syringe consisting of barrel, plunger rod, and plunger	Different: The subject device contains lubricant. This is evaluated through performance and biocompatibility testing. It does not raise new questions of safety and effectiveness for the subject device when compared to the predicate.
Materials	Barrel - Copolyester	Barrel – Polypropylene	Different: The differences in device material are not expected to impact safety or effectiveness. This is evaluated through biocompatibility testing. It does not raise new questions of safety and effectiveness for the subject device when compared to the predicate.
	Gasket – Elastomer	Plunger - Rubber	
	Plunger - Polypropylene	Plunger rod - Polypropylene	
	Lubricant - Silicone	N/A	
Syringe Size	0.7 mL, 1 mL	1 mL	Different: The subject device also comes in a size smaller than 1 mL, which is not uncommon for other syringes in this classification and does not raise safety concerns.
Connection Type	Luer-Lock tip	Luer-lock type	Same
Dead Space specification	≤ 0.023mL	≤ 0.023mL with 95% confidence/95% reliability	Same
Sterilization and Shelf Life	Gamma Sterilization 5 years	EO gas 3 years	Different. The subject device has been validated in accordance with FDA recognized standards and therefore it does not raise new questions of safety and effectiveness for the subject device when compared to the predicate.
Biocompatibility	Conforms to the requirements of ISO 10993	Cytotoxicity Sensitization	Different: The subject device has undergone

	series standards. Cytotoxicity Hemolysis Pyrogen test Intracutaneous reactivity test Skin sensitization test Acute systemic toxicity test Bacterial Endotoxins Test (USP39<85>) Sterility test (ISO 11737-2) USP<788>	Irritation Acute Systemic Toxicity Material-Mediated Pyrogenicity Hemocompatibility USP 39, <71> Sterility Test USP 39, <85> Bacterial Endotoxins Test	additional testing to support the biocompatibility of the device. This does not raise new questions of safety and effectiveness
Performance Data	ISO 7886-1:2017 ISO 80369-7:2021	ISO 7886-1 ISO 80369-7:2016	Same

Non-Clinical Tests Summary:

The TSK Syringe underwent biocompatibility testing according to the following:

ISO 10993-1:2018/Cor1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 10993-4:2017 Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood

ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

ISO 10993-18:2020/A1:2022 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process AMENDMENT 1

ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

ISO 7886-1 Second edition 2017-05 Small-bore connectors for liquids and gases in healthcare applications - Part 7 Connectors for intravascular or hypodermic applications

ISO 7886-1:2017 Second Edition 2017-05 Sterile hypodermic syringes for single use: Syringes for manual use,

ISO 80369-7:2021 Second Edition 2021-05 Small bore connectors for liquids and gases in healthcare applications: Connectors for intravascular or hypodermic applications,

USP<788> Particulate Matter in Injections

Bench testing was conducted according to the following performance standards:

ISO 7885-1: 2017 Sterile hypodermic syringes for single use

ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

The TSK Syringe was sterilized in accordance with the following:

ISO 11137-1:2006/Amd 2:2018	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
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
ISO 4180:2019	Packaging - Complete, filled transport packages - General rules for the compilation of performance test schedules
ASTM F 1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
ISO 7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
ISO 80369-7	Small bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications.
USP39<85>	Bacterial Endotoxins

Test samples are representative of finished devices including sterilization.

The TSK Syringe met all specified criteria and did not raise new safety or performance questions when compared to the predicate device.

Conclusion:

The results of non-clinical testing demonstrate that the TSK Syringe is substantially equivalent to, and is as safe and effective as, the predicate device for its intended use.