July 24, 2025

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

Re: K250284
Trade/Device Name: TSK SELECT™ Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI, QNS
Dated: June 22, 2025
Received: June 23, 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,

Shruti N. Mistry -S

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)*
K250284

Device Name
TSK SELECT™ Needle

Indications for Use *(Describe)*

The TSK SELECT™ Needle is indicated for subcutaneous injections of pharmaceutical products, or for withdrawal of fluids.

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.

K250284 510(k) Summary

TSK SELECT™ Needle

Submitter:

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Date:

July 24, 2025

Correspondent:

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Dr. Anna Galea
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Device Trade Name:	TSK SELECT™ Needle
Common Name:	Hypodermic single lumen needle, Low dead space needle
Classification Name:	Hypodermic single lumen needle
Regulation Number:	880.5570
Product Codes:	FMI, QNS
Regulation Class:	II
Predicate:	K210444: EZ-Injec LDV Sterile Safety Needle, Product Code QNS

Device Description Summary:

The TSK SELECT™ Needle is designed to provide a means of fluid injection and aspiration to and from the body. It is a single lumen needle intended for use with a luer-tip syringe. The TSK SELECT™ Needle consisting of a stainless-steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) made of polypropylene, or polycarbonate, depending on the hub type, designed to be connected with a male luer fitting of a syringe. The TSK SELECT™ Needle is intended for manual use by health care professionals for administration of fluids. The TSK SELECT™ Needle is provided sterile, is single use only, non-toxic, non-pyrogenic, and sterilized by gamma irradiation.

The model numbers associated with the TSK SELECT™ Needle are presented in the table below. Some model numbers have two variations based on wall thickness:

TSN-xxxxxx: Thin Wall (TW)
TSN-xxxxxxE: Extra Thin Wall (ETW)
TSN-xxxxxxR: Regular Wall (RW)

Note: All needles are Model TSN

Product Code	Nominal outer diameter (mm)	Gauge size (G)	Needle Length (mm)	Color Code		Wall Thickness	Device Description
				Label	Hub		
TSN-050013	0.50	25	13	Orange	Natural	TW	TSK SELECT Needle 25G(0.40mm) x 13mm TW
TSN-050025R	0.50	25	25	Orange	Natural	RW	TSK SELECT Needle25G(0.50mm) x 25mm RW
TSN-040013	0.40	27	13	Medium grey	Natural	TW	TSK SELECT Needle27G(0.50mm) x 13mm RW
TSN-040019R	0.40	27	19	Medium grey	Natural	RW	TSK SELECT Needle 27G(0.40mm) x 19mm TW
TSN-030004	0.30	30	4	Yellow	Natural	TW	TSK SELECT Needle 30G(0.30mm) x 4mm TW
TSN-030009	0.30	30	9	Yellow	Natural	TW	TSK SELECT Needle 30G(0.30mm) x 9mm TW
TSN-030013	0.30	30	13	Yellow	Natural	TW	TSK SELECT Needle 30G(0.30mm) x 13mm TW
TSN-030013E	0.30	30	13	Yellow	Natural	ETW	TSK SELECT Needle 30G(0.30mm) x 13mm ETW
TSN-025004	0.25	31	4	White	Natural	TW	TSK SELECT Needle 31G(0.25mm) x 4mm TW
TSN-025009	0.25	31	9	White	Natural	TW	TSK SELECT Needle 31G(0.25mm) x 9mm TW
TSN-025013	0.25	31	13	White	Natural	TW	TSK SELECT Needle 31G(0.25mm) x 13mm TW
TSN-023004	0.23	32	4	Deep green	Natural	TW	TSK SELECT Needle 32G(0.23mm) x 4mm TW
TSN-023009	0.23	32	9	Deep green	Natural	TW	TSK SELECT Needle 32G(0.23mm) x 9mm TW
TSN-023013	0.23	32	13	Deep green	Natural	TW	TSK SELECT Needle 32G(0.23mm) x 13mm TW
TSN-020004	0.20	33	4	Black	Natural	TW	TSK SELECT Needle 33G(0.20mm) x 4mm TW
TSN-020004R	0.20	33	4	Black	Natural	RW	TSK SELECT Needle 33G(0.20mm) x 4mm RW
TSN-020009	0.20	33	9	Black	Natural	TW	TSK SELECT Needle 33G(0.20mm) x 9mm TW
TSN-020009R	0.20	33	9	Black	Natural	RW	TSK SELECT Needle 33G(0.20mm) x 9mm RW
TSN-018004	0.18	34	4	Orange	Natural	TW	TSK SELECT Needle 34G(0.18mm) x 4mm TW

TSN-018009	0.18	34	9	Orange	Natural	TW	TSK SELECT Needle 34G(0.18mm) x 9mm TW

Indications for Use:

The TSK SELECT™ Needle is indicated for subcutaneous injections of pharmaceutical products, or for withdrawal of fluids.

Indications for Use Comparison:

The indication for use is the equivalent to that of the predicate. Please refer to the Table below in Technological Comparison.

Technological Comparison:

The device has the same technological characteristics and materials as the predicate. Testing on the subject device is the same as that on the predicate.

Comparison of Subject Device to Predicate Device	**Subject Device TSK Select Needle**	**Predicate Device EZ-Injec LDV Sterile Safety Needle (K210444)**	**Discussion**
Manufacturer	TSK Laboratory-Japan	POONGLIM PHARMATECH INC.	
Regulation	21 CFR 880.5570	21 CFR 880.5570	
Product Code	FMI, QNS	QNS	
Class	Class II	Class II	
Classification Name	Hypodermic single lumen needle	Low Dead Space Needle, Single Lumen, Hypodermic	
Indications for Use	The TSK SELECT™ Needle is indicated for subcutaneous injections of pharmaceutical products, or for withdrawal of fluids.	This product is intended for use to inject fluid into or withdraw fluids from parts of the body below the surface of the skin.	Same
Intended Use	The TSK SELECT™ Needle is intended for use with a syringe, for injection of a pharmaceutical product or draining of a fluid.	To inject fluid into or withdraw fluids from parts of the body below the surface of the skin.	Same
Intended User and Environment	Clinicians in a clinical setting	N/A	Different: This does not raise new or different questions of safety and effectiveness as this just specifies the intended user for the subject device.
Device Components	Needle, Needle Hub, Needle Cap. Designed to fit standard luer fittings	Needle, Needle Hub and protector	Different: This does not raise new or different questions of safety and effectiveness as the device design has been adequately supported by verification and validation data.
Materials-Needle	Stainless Steel	Stainless Steel	Same

Needle Hub **Lubricant** **Adhesive** **Needle Cap**	Polycarbonate	Polypropylene	Different: The subject device has been verified in accordance with the FDA recognized standards and therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.
	Silicone	N/A	Different: The subject device has been verified in accordance with the FDA recognized standards and therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.
	Epoxy	Epoxy	Same
	Polyethylene	Polypropylene	Different: The subject device has been verified in accordance with the FDA recognized standards and therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.
Needle Gauge	25G – 34G	25G	Different: The subject device has been verified in accordance with the FDA recognized standards and therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.
Needle Length (exposed)	4mm, 9mm, 13mm, 19mm, 25mm	25mm	Different: The subject device has been verified in accordance with the FDA recognized standards and therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.
Needle Tip	Regular Bevel	"Bevel"	Different: The subject device has been verified in accordance with the FDA recognized standards and therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.
Dead Volume	≤0.0054ml	≤0.0054ml	Same
Safety Feature	No safety feature	Yes- safety feature	Different: The subject device does not have a safety feature. This does not raise new or different questions of safety and effectiveness.
Syringe Compatibility	Luer-lock, Luer Slip ISO 80369-7 compliant	Luer Lock, Luer Slip ISO 80369-7 compliant	Same
Needle Color Coding	Conforms to ISO 6009	N/A	Different: The subject device is compliant to ISO 6009 for the needle color coding, therefore, this does not raise a new or

			different question of safety and effectiveness.
Sterilization and Shelf Life	Provided Sterile, Single-Use 100 individual needles packaged in a hardcase and then packaged into a shelf carton. Sterilization Method: Gamma Irradiation SAL: 10^{-6} Shelf-life: 5 years	Sterilization Method: EO gas SAL: 10^{-6} Shelf-life: 5 years	Different: The subject device has been validated in accordance with the FDA recognized standards and therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.
Biocompatibility	ISO 10993-1 (Biological Evaluation)	ISO 10993-1 (Biological Evaluation)	Same
	ISO 10993-4 (Hemocompatibility)	N/A	Different: The subject device has been validated in accordance with the FDA recognized standards and therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.
	ISO 10993-5 (Cytotoxicity)	Cytotoxicity	Same
	ISO 10993-10 (Sensitization)	Sensitization	Same
	ISO 10993-23 (Irritation: intracutaneous reactivity)	Irritation	Same
	ISO 10993-11 (Acute Systemic Toxicity)	Acute Systemic Toxicity	Same
	ISO 10993-11 (Pyrogen)	Material-Mediated Pyrogenicity	Same
	USP <788> Particulate Matter in Injections	USP <788> Particulate Matter in Injections	Same
Performance Data	Meets ISO 7864 Meets ISO 9626 Meets ISO 80369-7 Meets USP <788>	Meets ISO 7864 Meets ISO 9626 Meets ISO 23908 Meets ISO 80369-7 Meets USP <788>	Different: The subject device has done additional testing to support the verification of the device. This does not raise new or different questions of safety and effectiveness.

Subject device packaging and sterilization method is not the same as the predicate. However, the subject device has been validated in accordance with the FDA recognized standards and therefore it does not raise new question of safety and effectiveness for the subject device when compared to the predicate device.

Biocompatibility testing was performed to demonstrate that device material differences between the subject device and predicate do not raise new questions of safety and effectiveness.

Performance testing was conducted in accordance with ISO 7864, ISO 9626, ISO 80369-7, and USP <788> to demonstrate that subject device performance does not raise new questions of safety or effectiveness.

Non-Clinical Tests Summary and Conclusions:

The TSK SELECT™ Needle underwent bench testing in accordance with the following standards:

- ISO 7864:2016_Sterile hypodermic needles for single use
- ISO 9626:2016_Stainless steel needle tubing for the manufacture of medical devices
- ISO 80369-1:2018_Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements
- ISO 80369-7:2021_Small-bore connectors for liquids and gases in healthcare applications —Part 7:Connectors for intravascular or hypodermic applications
- USP<788> Particulate matter in injections

The TSK SELECT™ Needle was sterilized in accordance with the following standards:

- ISO 11137-1:2006/Amd2:2018_Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices Amendment 2
- ISO 11737-2:2013/A1:2022_Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 11137-4_Sterilization of health care products - Radiation - Part 4: Guidance on process control
- ISO 11737-1:2018/A1:2021_Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- ISO 11737-2:2019_Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 11607-1:2019_Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2_Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

The TSK SELECT™ Needle also passed biocompatibility tests in the following categories:

- Biological Evaluation
- Hemocompatibility
- Cytotoxicity
- Sensitization
- Irritation: intracutaneous reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Particulate Matter in Injection

The biocompatibility tests were performed in accordance with the following standards:

- 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 10993-10:2021_Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
- 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

Conclusion

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