July 1, 2025

PAJUNK GmbH Medizintechnologie
Christian Quaß
Director Regulatory Affairs
Karl-Hall-Str. 1
Pajunkstr. 1
Geisingen, BW 78187
Germany

Re: K243690
Trade/Device Name: SonoMSK
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: May 28, 2025
Received: May 28, 2025

Dear Christian Quaß:

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,

TING SONG -S

for
Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

Submission Number *(if known)*

K243690

Device Name

SonoMSK

Indications for Use *(Describe)*

SonoMSK anaesthesia conduction needles enhanced for ultrasound visibility are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia.

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.

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USA

08 510(k) Summary

Registrations USA

510(k) Summary as required by 21 CFR 807.92(c).

Date of Preparation: 2025-05-22

Document Control Number: K243690

510(k) owner:	PAJUNK® GmbH Medizintechnologie Karl-Hall-Str. 1/ Pajunkstr. 1 78187 Geisingen Baden-Wuerttemberg, Germany Fon: +49(0)7704-9291-586 Fax: +49(0)7704-9291-605 Establishment Registration Number: **9611612**
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FEI Number*: 3004076349

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Contract Sterilizer: Sterigenics Germany GmbH
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Germany, Hessen
Establishment Registration Number: 3002807090

2nd Contract Sterilizer: HA2 MEDIZINTECHNIK GMBH
Am Bahndamm 11
Halberstadt Saxony-Anhalt, DE 38820
Registration Number: 3009039068
FEI Number*: 3009039068

Device Name and Classification

Device Name:	SonoMSK
Premarket Notification Number:	**K243690**
Classification Name:	Anesthesia Conduction Needle
Classification Reference:	**21 CFR § 868.5150**
Product Code:	BSP
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology

Sterilization Method:	Ethylene Oxide disposable device, supplied sterile to the end user and non-sterile intended to be sterilized prior to use to re-packagers/ medical device manufacturers
Contract Sterilizer:	Sterigenics Germany GmbH Kasteler straße 45 65203 Wiesbaden Germany, Hessen Establishment Registration Number: 3002807090
Additional Contract Sterilizer:	HA2 MEDIZINTECHNIK GMBH Am Bahndamm 11 Halberstadt Saxony-Anhalt, DE 38820 Registration Number: 3009039068 FEI Number*: 3009039068

Changes to Device: Predicate Device

Device Name:	SonoTAP, Tuohy SONO
Premarket Notification Number:	**K113207**
Classification Name:	Anesthesia Conduction Needle
Classification Reference:	**21 CFR § 868.5150**
Product Code:	BSP
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology
Sterilization Method:	Ethylene Oxide disposable device, supplied sterile to the end user and non-sterile intended to be sterilized prior to use to re-packagers/ medical device manufacturers

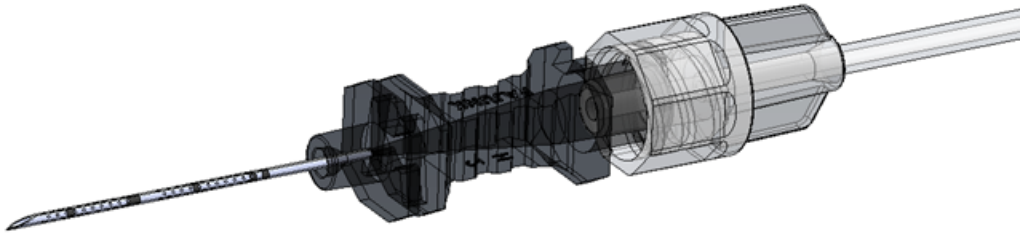
Contract Sterilizer:	Sterigenics Germany GmbH Kasteler straße 45 65203 Wiesbaden Germany, Hessen Establishment Registration Number: 3002807090

Changes to Device: Reference Device

Device Name:	SonoBlock, SonoBlock II
Premarket Notification Number:	**K241954**
Classification Name:	Anesthesia Conduction Needle
Classification Reference:	**21 CFR § 868.5150**
Product Code:	BSP
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology
Sterilization Method:	Ethylene Oxide disposable device, supplied sterile to the end user and non-sterile intended to be sterilized prior to use to re-packagers/ medical device manufacturers
Contract Sterilizer:	Sterigenics Germany GmbH Kasteler straße 45 65203 Wiesbaden Germany, Hessen Establishment Registration Number: 3002807090
Additional Contract Sterilizer:	HA2 MEDIZINTECHNIK GMBH Am Bahndamm 11 Halberstadt Saxony-Anhalt, DE 38820 Registration Number: 3009039068 FEI Number*: 3009039068

1 Narrative Device Description

The subject device, the SonoMSK needle is a single-use anesthesia conducting needle intended for for the transient delivery of anesthetics to provide regional anesthesia and analgesia.
The SonoMSK needle is intended for use under ultrasound guidance. Visibility under ultrasound is enhanced by CornerStone reflectors as cleared by FDA in several Premarket Notification Submissions.
The SonoMSK needle is equipped with an injection tube. The distal connection of the tube is equipped with a LUER Connector according to ISO 80369-7.



The device in focus is a single use device and has an intended time of use up to 24 hours acc. EO-residuals acc. DIN EN ISO 10993-7. The standard time of use is less than 60 minutes.
The SonoMSK cannulas are not for intrathecal use.
The SonoMSK cannulas are produced at PAJUNK® GmbH Medizintechnologie in Geisingen, Germany.

2 Determination of Substantial Equivalence

Intended Use Predicate Device (510(K) Predicate)

The cannulas/ needles for anesthesia and analgesia enhanced for ultrasound visibility – Tuohy Sono, Sono TAP, Quincke Sono, Chiba Sono, SPROTTE® Sono and Crawford Sono – are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of a catheter.

Intended Use Subject Device

SonoMSK anesthesia conduction needles enhanced for ultrasound visibility are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia.

Discussion

The Intended Use of the Predicate device and of the subject device is substantially equivalent. The Subject device and the predicate device both offer localization via ultrasound as it is state of the art and well established.

Conclusion: substantially equivalent

3 Technical Description

Substantial Equivalence: Tabulatory Outline

Characteristics	Subject Device SonoMSK **Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen**	Predicate Device K113207 SonoTAP **Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen**
Picture		
Needle Tubing	Stainless Steel 1.4301	Stainless Steel 1.4301
Tip	bevelled tip, bevelled tip with relief grind	Tuohy, Facet
Hub	Copolyester (Tritan MX731) (Indirect Patient Contact)	Copolyester (Tritan MX731) (Indirect Patient Contact)
Coating	Silicone (Dow Corning 360 Medical Fluid 12500 cSt), Silicone thinner (Dow Corning Q7-9180 Silicone Fluid 1.0 cSt)	Silicone (Dow Corning 360 Medical Fluid 12500 cSt), Silicone thinner (Dow Corning Q7-9180 Silicone Fluid 1.0 cSt)
US-enhancement	Cornerstones	Cornerstone
Graduation	Tampapur TPU	Tampapur TPU
Bonding Technology Needle-to-Hub	glued	glued
Glue	(Epoxy adhesive - Araldite 2011), alternatively: UV adhesive (Loctite AA 3921)	(Epoxy adhesive - Araldite 2011), alternatively: UV adhesive (Loctite AA 3921)
Injection tube	PVC (MED7536), PC (HP4), MABS (Terlux 2802)	PVC (MED7536), PC (HP4), MABS (Terlux 2802)
Diameter	22G-27G	18G - 24G

Characteristics	Subject Device SonoMSK **Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen**	Predicate Device K113207 SonoTAP **Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen**
Length	25mm-150mm	40mm - 150 mm
Connectivity	ISO 80369-7 (LUER)	ISO 80369-7 (LUER)
Packaging	Tyvek, Foil, chromo-duplex board Alternatively: Paper, Foil	Tyvek, Foil, chromo-duplex board
Biocompatibility	Complies with ISO10993-series as required by « Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" », Docket Number : FDA-2013-D-0350	
Sterilization Method	Ethyleneoxide	Ethyleneoxide
Sterility Assurance Level	SAL=10^{-6}	SAL=10^{-6}
Sterilization Service Provider	Sterigenics, Wiesbaden HA2 Medizintechnik, Halberstadt	Sterigenics, Wiesbaden
Shelf Life	60 month from sterilization	60 month from sterilization

4 Substantial Equivalence Discussion

The predicate device and the subject device have some characteristical differences:

a) tip -> The modified tip of the SonoMSK is designed to enhance visibility under ultrasound and facilitate precise positioning without increasing tissue trauma. Bench testing (needle insertion force and tissue resistance) demonstrated equivalent or reduced insertion forces compared to the predicate. Moreover, the tip design remains within standard clinical geometries used in peripheral nerve block procedures and does not introduce any novel risks.
Therefore, the modified tip does not adversely affect patient safety and maintains effectiveness in achieving targeted nerve access.

b) diameter -> All offered diameters are within commonly used clinical ranges and comply with ISO 9626

standards for stainless steel needles. The variation in diameter allows customization for specific anatomical approaches (e.g., superficial vs. deep nerves) but does not introduce new risks.

c) length -> The availability of multiple needle lengths allows the clinician to select the appropriate configuration based on patient size, depth of target, and anatomical location. All lengths are within clinically accepted ranges for peripheral and musculoskeletal nerve access and follow design precedents established in similar legally marketed needles.

The predicate devices, the SonoTAP needles, are packed with Tyvek and foil and sterilized with Ethyleneoxide at Sterigenics, Germany.

The subject devices, the SonoMSK needles, are packed with Tyvek and foil as well as optionally with Medical Paper and foil.

Furthermore, the subject devices are sterilized at Sterigenics in Wiesbaden as well as optionally at HA2 Medizintechnik in Halberstadt.

The main differences which are subject to this premarket submission are

a) the addition of a sterilization facility and
b) the addition of an alternative packaging material.

In order to verify substantial equivalence of the sterilization process a sterilization validation according ISO 11135 has been performed and successfully accomplished. The sterility assurance level of 10^{-6} has been successfully validated at both facilities: Sterigenics and HA2.

In order to verify substantial equivalence of the packaging exhaustive packaging and shelf life tests have been performed. Both, medical paper and Tyvek have been validated and verified to allow sterilization using EtO and to maintain sterility after a shelf life of 60 month after sterilization.

5 Performance Testing

The needles subject to this premarket submission are subject to performance testing prior to release as well as after shelf life scenario of 5 years.

There is no impact of the change subject to this submission (additional optional sterilization provider, additional optional packaging) on the performance of the needle as defined in the user requirements specification.

Especially the hub to needle bonding requirements remain unaffacted. The processes are still valid and reliable.

The test listed below are standard tests performed on a regular basis as well as type tests performed after design transfer.
Tests are performed to comply with the international standards listed below in the respectively most current version:
ISO 9626 Stainless steel needle tubing for manufacture of medical devices
ISO 7864 Sterile hypodermic needles for single use - Requirements and test methods
ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
ISO 80369-20 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods

5.1 ISO 7864

The following sections have been tested:

section	Pass / Fail
4.3 Cleanliness	Passed
4.4 Limits for acidity or alkalinity	Passed
4.5 Limits for extractable metals	Passed
4.10 Needle Tube	Passed
4.11 Needle point	Passed
4.12 Bond between hub and needle tube	Passed
4.13 Patency of lumen	Passed

5.2 ISO 9626

The following sections have been tested:

section	Pass / Fail
5.2 Surface finish and visual appearance	Passed
5.3 Cleanliness	Passed
5.4 Limits for acidity and alkalinity	Passed
5.5 Size designation	Passed
5.6 Dimensions	Passed
5.7 Sample size	Passed
5.8 Stiffness	Passed
5.9 Resistance to breakage	Passed
5.10 Resistance to corrosion	Passed

5.3 ISO 80369

The following sections of the 80369-7 have been tested:

section	Pass / Fail
7.1 Fluid Leakage	Passed
7.2 Air Leakage	Passed
7.3 Stress Cracking	Passed
7.4 Separation Axial Load	Passed
7.5 Unscrewing	Passed
7.6 Overriding	Passed

6 Sterilization

The contract sterilizer and the sterilizing process are identical to the process and sterilizer used for all PAJUNK® - manufactured devices which are already cleared for market or exempt.

Sterilization parameters are:

SAL	10^{-6}
Type of gas	Ethylene Oxide 99,99%

Sterilization has been validated according to ISO 11135-1 Overkill Approach (1 sublethal cycle, 2 half cycle, 1 full cycle)
Residuals of EO and ECH are in compliance with ISO 10993-7.

Cleaning and Sterilization method, which ensures an SAL of 10^{-6} as well as compliance with limits for chemical burden, bioburden, pyroburden (i.e. LAL) and EtO-residuals as well as shelf life have been validated and are safe and effective.

The limits listed below are met by each device:
Limits for Residuals: 25ppm = 25µg/(g/device) of Ehyleneoxide (EO); 25ppm = 25µg/(g/device) Ethylene chlorhydrine

7 Shelf Life

Efficacy of sterile product´s lifecycle has been validated using process most challenging worst case devices.

Sterility tests have been performed using process most challenging worst case devices with similar characteristics made from the same material after 5 years. The devices were found to be sterile after 5 years, the sterile barrier system is efficient.

Performance of the device (LUER connection, stability of bonding connections, needle´s bending rigidity) has been tested. There is no decrease in performance after 5 years.
Shelf-life is set to 5 years.

8 Biocompatibility

All products comply with ISO 10993-1 and with FDA´s guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Therefore, based on sterilization validation and residuals validation the kits also are considered to be biocompatible.

9 Technology Characteristics

Both, the subject device and the predicate device, consist of identical components.

10 Conclusion

The comparison between the predicate device and the subject device of this submission focussed on the validated sterilization process and the shelf life testing demonstrates that the subject device can be optionally in addition packed using medical paper and can be optionally sterilized at the alternative sterilization service provider at an SAL of 10^{-6}.

The results demonstrate that the subject device is substantially equivalent and as safe, as effective, and performs as well as the predicate device.