June 25, 2025

PAJUNK GmbH Medizintechnologie
Chiara Meyer
Specialist Regulatory Affairs
Karl-Hall-Str. 1
Pajunkstr. 1
Geisingen, BW 78187
Germany

Re: K250774
Trade/Device Name: SPROTTE® STANDARD (LUER/ NRFit®) Lumbar Puncture
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: March 14, 2025
Received: March 14, 2025

Dear Chiara Meyer:

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,

Bradley Q. Quinn -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250774

Device Name
SPROTTE® STANDARD (LUER/ NRFit®) Lumbar Puncture

Indications for Use *(Describe)*
The SPROTTE® STANDARD (LUER/ NRFit®) lumbar puncture needles are intended to gain entry into or puncture the spinal cavity permitting injection/ withdrawal of fluids for purposes of diagnostic lumbar puncture, myelography/ discography.

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: 2025-06-18

Document Control Number: K250774

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**
Submitter Information/ production site:	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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USA Contact:	PAJUNK MEDICAL SYSTEMS 4575 Marconi Dr. Alpharetta, GA 30005 Registration Number: 3004076349 FEI Number*: 3004076349
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Phone: 001-770-4936832
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Contract Sterilizer:

Sterigenics Germany GmbH
Kasteler straße 45
65203 Wiesbaden
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:	SPROTTE® STANDARD (LUER/ NRFit®) lumbar punkture needles
Premarket Notification Number:	**K250774**
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:	Sprotte NRFit™, Quincke NRFit™
Premarket Notification Number:	K160294
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:	SPROTTE® STANDARD (LUER/ NRFit®)
Premarket Notification Number:	**K241953**
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 **SPROTTE® STANDARD (LUER/ NRFit®)** anaesthesia conduction needle is a single-use anaesthesia conducting intended for administer anesthetic agent to the spinal space.
The SPROTTE® cannulas are equipped with a stylet as well as optional with an Introducer. It is available with a LUER respectively with a NRFit® hub. The LUER is either a standard hub, a magnifying hub or a 2.G hub. The cannula tube is straight. The distal connection of the hub is either equipped with a LUER Connector according to ISO 80369-7 or a NRFit-Connector according to ISO 80369-6.

1.1 Differences among models

SPROTTE® STANDARD
The SPROTTE® cannulas consist of a stainless-steel tube, a Tritan hub and are equipped with a stylet. The cannulas have a LUER hub. The LUER hub is either a standard hub or magnifying. The cannula has a atraumatic, noncutting, symmetrical pencil point tip with a side-hole opening. The cannula tube is straight.

The different technical specifications are the the diameter, the length and if it comes with an introducer. The diameter has a range from 18G-22G. The length has a range from 90mm-200mm. The introducer is optional. It comes in a diameter range from 1,0mm-1,65mm and a length range from 30mm-40mm

SPROTTE® STANDARD NRFit®
The SPROTTE® cannulas consist of a stainless steel tube, a Tritan hub and are equipped with a stylet. The cannulas have a NRFit® hub. The NRFit® hub is a magnifying hub. The cannula has a atraumatic, noncutting, symmetrical pencil point tip with a side-hole opening. The cannula tube is straight.

The different technical specifications are the the diameter, the length and if it comes with an introducer. The diameter has a range from 20-22G. The length has a range from 103mm-150mm. The introducer is optional. It comes in a diameter range from 1,00mm-1,20mm and a length range from 30mm-40mm

2 Determination of Substantial Equivalence

Intended Use Predicate Device (510(K) Predicate)

The SPROTTE® NRFit™, Quincke NRFit™ lumbar puncture needles are intended to gain entry into or puncture the spinal cavity permitting injection (including anesthesia) / withdrawal of fluids for purposes of diagnostic lumbar puncture, myelography/ discography procedures.

The device is intended for adult and pediatric patients.

Intended Use Subject Device

The SPROTTE® STANDARD (LUER/ NRFit®) lumbar puncture needles are intended to gain entry into or puncture the spinal cavity permitting injection/ withdrawal of fluids for purposes of diagnostic lumbar puncture, myelography/ discography.

Discussion

The Intended Use of the Predicate device and of the subject device is substantially equivalent.

Conclusion: substantially equivalent

3 Technical Description

Substantial Equivalence: Tabular Outline

Characteristics	Subject Device Sprotte Standard (Luer/ NRFit) Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K160294 Sprotte NRFit Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Reference Device K241953 Sprotte Standard (Luer/ NRFit) Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen
Picture			
Needle Tubing	Stainless steel 1.4301	Stainless steel 1.4301	Stainless steel 1.4301
Stylet	Stainless steel 1.4310	Stainless steel 1.4310	Stainless steel 1.4310
Introducer Tubing	Stainless steel 1.4301	Stainless steel 1.4301	Stainless steel 1.4301
Tip Cannula	Sprotte tip	Sprotte tip	Sprotte tip
Tip Introducer	Facet tip	Facet tip	Facet tip
Cannula Hub	PC (Lexan 164R-112) Copolyester (Tritan MX731)	PC (Lexan 164R-112) Copolyester (Tritan MX731)	PC (Lexan 164R-112) Copolyester (Tritan MX731)
Introducer hub	Copolyester (Tritan MX731)	PC (Lexan 164R-112)	Copolyester (Tritan MX731)
Stylet Knob	PC (Lexan 164R-112)	PC (Lexan 164R-112)	PC (Lexan 164R-112)
Graduation	For cannulas 100mm length and longer	For cannulas 100mm length and longer	For cannulas 100mm length and longer

Bonding Technology Needle-to-Hub Cannula	Adhesive bonding	Adhesive bonding	Adhesive bonding
Bonding Technology Needle-to-Hub Introducer	Adhesive bonding Overmolding	Adhesive bonding	Adhesive bonding Overmolding
Glue Cannula	Epoxy resin (Araldite 2011) UV Adhesive (Dymax 1406-M)	Epoxy resin (Araldite 2011) UV Adhesive (Dymax 1406-M)	Epoxy resin (Araldite 2011) UV Adhesive (Dymax 1406-M)
Glue Stylet	Epoxy resin (Araldite 2011)	Epoxy resin (Araldite 2011)	Epoxy resin (Araldite 2011)
Glue Introducer	Epoxy resin (Araldite 2011) UV Adhesive (Dymax 1406-M)	Epoxy resin (Araldite 2011)	Epoxy resin (Araldite 2011) UV Adhesive (Dymax 1406-M)
Diameter	18-22G	18G-29G	22G-29G
Length	90mm-200mm	50-150	25-200mm
Connectivity	ISO 80369-6 (NRFit) ISO 80369-7 (LUER)	ISO 80369-6 (NRFit)	ISO 80369-6 (NRFit) ISO 80369-7 (LUER)
Packaging	Tyvek, Foil, chromo-duplex board Alternatively: Paper, Foil	Tyvek, Foil, chromo-duplex board	Tyvek, Foil, chromo-duplex board Alternatively: Paper, Foil
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 Sterilization	Ethyleneoxide Sterilization	Ethyleneoxide Sterilization
Sterility Assurance Level	SAL=10-6	SAL=10-6	SAL=10-6
Sterilization Service Provider	Serigenics, Wiesbaden HA2 Medizintechnik, Halberstadt	Serigenics, Wiesbaden	Serigenics, Wiesbaden
Shelf Life	60 month from sterilization	60 month from sterilization	60 month from sterilization

4 Substantial Equivalence Discussion

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

a) 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 but does not introduce new risks.

b) 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 differences between the two predicate devices result from the area of application. In lumbar puncture, cerebrospinal fluid (CSF) is primarily taken or pressure is measured. A slightly larger inner diameter enables a faster and stronger CSF flow so that samples can be obtained in a reasonable amount of time.
spinal anesthesia, local anesthetic is injected into the subarachnoid space. Because only relatively small volumes need to be administered, needles with a much finer outer diameter can be used.

The subject device can be either directly injection moulded or glued. The predicate device technology for hub-to-needle bonding is glueing. Both technologies - direct molding as well as glueing - are standard technologies.

Also the connectivity of the subject device can be either LUER or NRFit. The connectivity of the predicate device is NRFit. Both connectivity's - LUER as well as NRFit - are state of the art.

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

The subject devices, the Sprotte STANDARD (LUER/ NRFit) 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.

Both differences have been cleared in K241953 Sprotte STANDARD (LUER/ NRFit).

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

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
4.12 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 80369-6

The following sections been tested:

section	
6.1 Fluid Leakage	Passed
6.2 Air Leakage	Passed
6.3 Stress Cracking	Passed
6.4 Separation Axial Load	Passed
6.5 Unscrewing	Passed
6.6 Overriding	Passed

5.4 ISO 80369-7

The following sections been tested:

section	
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

Efficiency 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/ NRFit 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 focused 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.
Based on current in-process testing regularly conducted, safe performance of the SPROTTE® STANDARD (LUER/ NRFit®) needle is demonstrated.