



June 27, 2025

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

Re: K243682
Trade/Device Name: SonoPlex STIM; SonoPlex II
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: May 27, 2025
Received: May 27, 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

Indications for Use

Submission Number (if known)

K243682

Device Name

SonoPlex STIM;
SonoPlex II

Indications for Use (Describe)

SonoPlex STIM and SonoPlex II Needles equipped with Cornerstone reflectors are used to puncture the tissue in order to gain entry and inject local anesthetics to induce regional anesthesia. An electrical stimulus may be applied to the needle via a cable and connector to assist the physician pinpoint the area of application.

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
PRASStaff@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."

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: K243682

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

Manufacturer/ Submitter Contact:

Christian G. H. Quass
Director Regulatory Affairs, Safety Officer
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-602
E-Mail: christian.quass@pajunk.com

Alternative Manufacturer/ Submitter Contact:

Chiara Meyer
Regulatory Affairs Specialist
Fon: +49(0)7704-9291-627
Fax: +49(0)7704-9291-602
E-Mail: chiara.meyer@pajunk.com

Premarket Notification Submission

USA Contact:

PAJUNK MEDICAL SYSTEMS
4575 Marconi Dr.
Alpharetta, GA 30005
Registration Number: 3004076349
FEI Number*: 3004076349

US-Official Correspondent

Marco Wohnig
President
PAJUNK Medical Systems
4575 Marconi Dr.
Alpharetta, GA 30005
Phone: 001-770-4936832
E-Mail: Marco.Wohnig@pajunk-usa.com

Contract Sterilizer:

Sterigenics Germany GmbH
Kasteler straÙe 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:	SonoPlex STIM, SonoPlex II
Premarket Notification Number:	K243682
Classification Name:	Anesthesia Conduction Needle
Classification Reference:	21 CFR § 868.5150
Product Code:	BSP
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology

Premarket Notification Submission

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 straÙe 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:	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

Premarket Notification Submission

Contract Sterilizer:	Sterigenics Germany GmbH Kasteler straÙe 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

The subject device, the SonoPlex STIM and SonoPlex II needle is a single-use anaesthesia conducting needle intended for use peripheral nerve blocks.

The SonoPlex STIM and SonoPlex II 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. Additionally and optionally an electrical stimulus may be applied to the needle via a cable and connector to assist the physician pinpoint the area of application (also referred to as Dual Guidance).

The predicate device, the SonoBlock and SonoBlock II nerve block needle is a single-use anaesthesia conducting nerve block needle intended for performing peripheral nerve blocks.

The subject device as well as the predicate device have been cleared earlier by the Sponsor in K111374. The predicate device has also been cleared in K241954 to file a standalone 510(k) and to inform the Agency about additional options to be added to the device's manufacturing process.

K111374 in 2011 has been filed and cleared for ultrasound enhanced Parylene coated needles (Cornerstones) optionally equipped with an electrical cable for optional application of an electrical stimulus. These needles are optionally used for Dual Guidance: Ultrasound guidance and verification via electrical stimulus (while landmark technique without ultrasound and electrical stimulus is also widespread).

Since 2011 some alterations have taken place after clearance:

- Needles formerly named SonoPlex (Ultrasound only) have been renamed to SonoBlock
- Hub-to-needle technology formerly cleared as gluing (2K and UV) has been optionally amended by direct injection moulding
- For injection moulding the material of the hub has been changed
- By direct overmoulding, the tube and where applicable the cable are directly moulded to the hub and one

Premarket Notification Submission

screw connection is substituted by this manufacturing step.

Each of these alterations followed FDA's Guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device". None of these alterations did result in additional hazards to the patient since the indications for use and the clinical technique have not been impacted.

Each of the alterations has been diligently verified and validated during design process and has been accompanied by risk management measures during manufacturing.

None of the alterations did impact the risk status or the labelling. Safety and effectiveness as well as efficacy of the device remain unaltered.

This Premarket Notification is intended to file a standalone 510(k) for the SonoPlex STIM and SonoPlex II needles and to inform the Agency about additional options to be added to the device's manufacturing process.

Subject to this 510(k) is

- **the validation of an additional optional sterilization service provider (HA2 Medizintechnik, Halberstadt, Establishment Registration number 3009039068)**
- **the validation of an additional optional packaging material (medical paper).**

Both, new sterilization service provider and additional packaging material, have been added to the Design History file and the Device master record in order to be able to package and sterilize the device using additional processes as an additional option.

Both, new sterilization service provider and additional packaging material, have been cleared earlier by the sponsor in K241954.

Both devices, the predicate SonoBlock and SonoBlock II as well as the subject SonoPlex STIM and SonoPlex II are manufactured by PAJUNK GmbH Medizintechnologie, the sponsor of this submission, in Geisingen, Germany.

Both devices, the predicate SonoBlock and SonoBlock II as well as the subject SonoPlex STIM and SonoPlex II share the same indications for use. The safety and effectiveness in localization options is substantially equivalent.

Apart from stimulation option both devices, the predicate device as well as the subject device, share identical required specifications for device performance as laid down in ISO 9626, ISO 7864, ISO 80369-series, ISO 10993-series and ISO 11135-series.

Premarket Notification Submission

Both devices, the predicate device as well as the subject device are manufactured in the same regulatory framework, e. g. Quality Management System (compliant with 21cfr820 and ISO 13485) using the same risk management system according to ISO 14971.

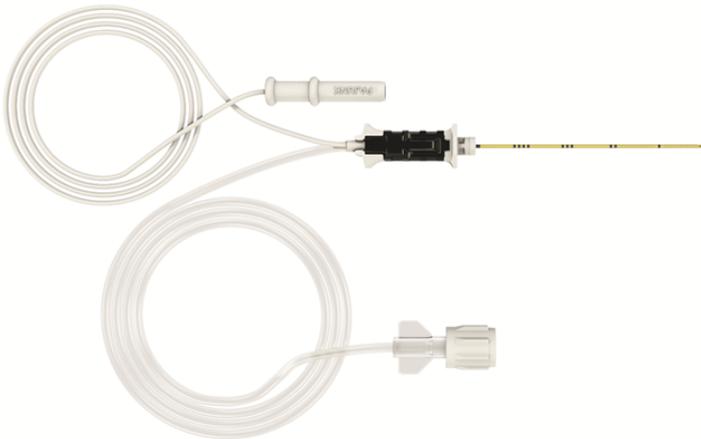
The SonoPlex STIM and SonoPlex II are also available in bulk non sterile. If appropriately packed and sterilized with Ethylene oxide according to the given sterilization parameters the technological parameters remain unchanged. However, final responsibility for sterilization validation remains with the customer of SonoPlex STIM and SonoPlex II purchased bulk non-sterile.

Premarket Notification Submission**1 Narrative Device Description**

The subject device, the SonoPlex STIM and SonoPlex II nerve block needle is a single-use anesthesia conducting needle intended to gain entry or puncture the tissue and inject anesthetics to induce regional anesthesia.

The SonoPlex STIM and SonoPlex II 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 SonoPlex STIM and SonoPlex II needle is equipped with an connecting cable, injection tube and NanoLine® coating (Parylene, no nanomaterials incorporated). The distal connection of the tube is either equipped with a LUER Connector according to ISO 80369-7 or a NRFit-Connector according to ISO 80369-6.



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 SonoPlex STIM and SonoPlex II cannulas are not for intrathecal use.

The SonoPlex STIM and SonoPlex II cannulas are produced at PAJUNK® GmbH Medizintechnologie in Geisingen, Germany.

2 Determination of Substantial Equivalence**Intended Use Predicate Device (510(K) Predicate)**

SonoBlock and SonoBlock II Needles equipped with Cornerstone reflectors are used to puncture the tissue in order to gain entry and inject local anaesthetics to induce regional anaesthesia.

Warning:

SonoBlock and SonoBlock II Needles are not intended for RF ablation or any other type of ablation procedure.

Premarket Notification Submission

Intended Use Subject Device

SonoPlex STIM and SonoPlex II Needles equipped with Cornerstone reflectors are used to puncture the tissue in order to gain entry and inject local anesthetics to induce regional anesthesia.

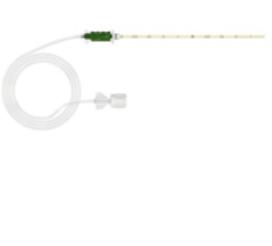
An electrical stimulus may be applied to the needle via a cable and connector to assist the physician pinpoint the area of application.

Discussion

The Intended Use of the Predicate device and of the subject device is substantially equivalent. The Predicate device offers localization via ultrasound as it is state of the art and well established. The Subject Device additionally offers electrical stimulus for localization (Dual Guidance). Both methods are state of the art and substantially equivalent.

Conclusion: substantially equivalent

3 Technical Description**Substantial Equivalence: Tabulatory Outline**

Characteristics	Subject Device SonoPlex STIM Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Subject Device SonoPlex II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K241954 SonoBlock Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K241954 SonoBlock II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen
Picture				
Needle Tubing	Stainless Steel 1.4301	Stainless Steel 1.4301	Stainless Steel 1.4301	Stainless Steel 1.4301
Tip	Tuohy, Quincke, Chiba, Facette	Tuohy, Quincke, Chiba, Facette	Tuohy, Quincke, Chiba, Facette	Tuohy, Quincke, Chiba, Facette

Premarket Notification Submission

Characteristics	Subject Device SonoPlex STIM Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Subject Device SonoPlex II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K241954 SonoBlock Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K241954 SonoBlock II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen
Hub	Copolyester (Tritan MX731) (Indirect Patient Contact)	Lustran/Guardian ABS 348 white 012002 (No Patient Contact)	Copolyester (Tritan MX731) (Indirect Patient Contact)	Lustran/Guardian ABS 348 white 012002 (No Patient Contact)
Coating	Parylene (NanoLine®), Silicone (Dow Corning 360 Medical Fluid 12500 cSt), Silicone thinner (Dow Corning Q7-9180 Silicone Fluid 1.0 cSt)	Parylene (NanoLine®), Silicone (Dow Corning 360 Medical Fluid 12500 cSt), Silicone thinner (Dow Corning Q7-9180 Silicone Fluid 1.0 cSt)	Parylene (NanoLine®), Silicone (Dow Corning 360 Medical Fluid 12500 cSt), Silicone thinner (Dow Corning Q7-9180 Silicone Fluid 1.0 cSt)	Parylene (NanoLine®), Silicone (Dow Corning 360 Medical Fluid 12500 cSt), Silicone thinner (Dow Corning Q7-9180 Silicone Fluid 1.0 cSt)
US-enhancement	Cornerstones	Cornerstone	Cornerstone	Cornerstone
Graduation	Tampapur TPU	Tampapur TPU	Tampapur TPU	Tampapur TPU
Bonding Technology Needle-to-Hub	glued	Directly molded	glued	Directly molded
Glue	(Epoxy adhesive - Araldite 2011), alternatively: UV adhesive (Loctite AA 3921)	n.a.	(Epoxy adhesive - Araldite 2011), alternatively: UV adhesive (Loctite AA 3921)	n.a.
Injection tube	PVC (MED7536), PC (HP4)	PVC (MED7536), PC (HP4)	PVC (MED7536), PC (HP4), ABS (Terlux 2802)	PVC (MED7536), PC (HP4)

Premarket Notification Submission

Characteristics	Subject Device SonoPlex STIM Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Subject Device SonoPlex II Manufacturer: PAJUNK® G mbH Medizintechnologie, Geisingen	Predicate Device K241954 SonoBlock Manufacturer: PAJUNK ® GmbH Medizintechnologie, Geisingen	Predicate Device K241954 SonoBlock II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen
Cable	PVC, Copper tin-plated, brass tin-plated, ABS (Guardian 348 - RAL9003) or Brass tin-plated, Copper tin-plated, cable (tinned wire), ABS PA-757 RAL 9003 / RAL1018	PVC, Copper tin-plated, brass tin-plated, ABS (Guardian 348 - RAL9003) or Brass tin-plated, Copper tin-plated, cable (tinned wire), ABS PA-757 RAL 9003 / RAL1018	n.a.	n.a.
Diameter	20G - 25G	20G - 25G	20G - 25G	20G - 25G
Length	40mm - 120 mm	40mm - 120 mm	40mm - 120 mm	40mm - 120 mm
Connectivity	ISO 80369-7 (LUER)	ISO 80369-7 (LUER) ISO 80369-6 (NRFit)	ISO 80369-6 (NRFit) ISO 80369-7 (LUER)	ISO 80369-6 (NRFit) ISO 80369-7 (LUER)
Packaging	Tyvek, Foil, chromo-duplex board Alternatively: Paper, Foil	Tyvek, Foil, chromo-duplex board Alternatively: Paper, Foil	Tyvek, Foil, chromo-duplex board Alternatively: Paper, Foil	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	Ethyleneoxide	Ethyleneoxide	Ethyleneoxide
Sterility Assurance Level	SAL=10 ⁻⁶	SAL=10 ⁻⁶	SAL=10 ⁻⁶	SAL=10 ⁻⁶

Premarket Notification Submission

Characteristics	Subject Device SonoPlex STIM Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Subject Device SonoPlex II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K241954 SonoBlock Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K241954 SonoBlock II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen
Sterilization Service Provider	Sterigenics, Wiesbaden HA2 Medizintechnik, Halberstadt	Sterigenics, Wiesbaden HA2 Medizintechnik, Halberstadt	Sterigenics, Wiesbaden HA2 Medizintechnik, Halberstadt	Sterigenics, Wiesbaden HA2 Medizintechnik, Halberstadt
Shelf Life	60 month from sterilization	60 month from sterilization	60 month from sterilization	60 month from sterilization

4 Substantial Equivalence Discussion

The Subject devices, the SonoPlex STIM and the SonoPlex II needles, are equipped with a cable for additionally pinpointing the needles position via an electrical stimulus called dual guidance (ultrasound and electrical stimulation). This is why a cable is attached to the hub in addition. The SonoBlock and SonoBlock II needles are equipped with ultrasound enhancing cornerstones without any cable since there is no stimulation. Both, ultrasound position guidance as well as ultrasound position guidance and electrical stimulation are state of the art. Both techniques are safe and effective.

Both, the subject device as well as the predicate device can be either directly injection moulded or glued. Both manufacturing technologies are safe and the processes are running stable. Both technologies are standard technologies.

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

The subject devices, the SonoPlex 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.

Premarket Notification Submission

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 ISO11135 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 unaffected. 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 80369-6 Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications

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

Premarket Notification Submission

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

Premarket Notification Submission

5.3 ISO 80369

The following sections of the 80369-6 have been tested:

section	Pass / Fail
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

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%

Premarket Notification Submission

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 Ethyleneoxide (EO); 25ppm = 25µg/(g/device) Ethylene chlorhydrine

The SonoPlex STIM and SonoPlex II are also available in bulk non sterile. If appropriately packed and sterilized with Ethylene oxide according to the given sterilization parameters the technological parameters remain unchanged. However, final responsibility for sterilization validation remains with the customer of spinal manometers purchased bulk non-sterile.

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.