September 11, 2024

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

Re: K241954
Trade/Device Name: SonoBlock; SonoBlock II
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: July 3, 2024
Received: July 3, 2024

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241954

Device Name
SonoBlock and SonoBlock II

Indications for Use *(Describe)*
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.

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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510_k

510(k) Summary

Registrations USA

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

Date of Preparation: 2024-09-06

Document Control Number: **K241954**

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

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 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:	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

Changes to Device: Predicate Device

Device Name:	SONO-SERIES CORNERSTONE TECHNIQUE
Premarket Notification Number:	K111374
Trade Name	SonoPlex, SonoPlex STIM, SonoLong
Classification Name:	SonoPlex, SonoPlex STIM, SonoLong
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

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

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

The SonoPlex and SonoPlex II nerve block needle is intended for use under ultrasound guidance. Visibility under ultrasound is enhanced by CornerStone reflectors. 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).

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. S 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:
- The SonoPlex STIM needles (Ultrasound and stimulation) have been renamed to SonoPlex
- 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 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.

The SonoBlock and SonoBlock ll has been added to K111374 SonoPlex and SonoPlex II as an Add to file following FDA´s Guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device". Both devices share the indications for use (Peripheral nerve block) and only differ by offering options for localization techniques. The SonoBlock II-series is directly injection moulded instead of glued (as the predicate is). This change does neither raise additional risk in performance nor new additional biocompatibility issues.
Since this modification/ additional device option does neither state a significant change nor does it pose any new risk to the patient this has been documented as an Add-to-file.

This Premarket Notification is intended to file a standalone 510(k) for the SonoBlock and SonoBlock ll 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 devices, the predicate SonoPlex and SonoPlex II as well as the subject SonoBlock and SonoBlock ll are manufactured by PAJUNK GmbH Medizintechnologie, the sponsor of this submission, in Geisingen, Germany.

Both devices, the predicate SonoPlex and SonoPlex II as well as the subject SonoBlock/ SonoBlock ll 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.
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 intended use as well as the basic technical specification of the needles which is relevant to clinical use is identical to the predicate devices and has been cleared in 510(k)s sent in earlier by the sponsor.

The clinical technique, the indications for use, the technical specification, the materials used, the sterility status (validation and sterility assurance level) as well as the biocompatibility status is identical.

None of the performance criteria is adversely affected by the device modification as it is subject to this submission.

This section of the submission contains the following information:

Contents

510(k) Summary

1 Determination of Substantial Equivalence

Intended Use Predicate Device (510(K) Predicate)

Needles/ cannulas equipped with Cornerstone reflectors as covered by the PAJUNK® Sonoseries SonoPlex STIM are used to puncture the tissue in order to gain entry and inject local anaesthetics to induce regional anaesthesia. An electrical stimulus may be applied to the needle via a cable and connector to assist the physician pinpoint the area of application.

Warning:
The PAJUNK GmbH Medizintechnologie needles of the Sono-series are not intended for RF ablation or any other type of ablation procedure.

Intended Use Subject Device

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.

Discussion

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

Conclusion: substantially equivalent

2 Technical Description

Substantial Equivalence: Tabulatory Outline

Characteristics	Subject Device SonoBlock II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Subject Device SonoBlock Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K111374 SonoPlex II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K111374 SonoPlex 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
Hub	Lustran/Guardian ABS 348 white 012002 (No Patient Contact)	Copolyester (Tritan MX731) (Indirect Patient Contact)	Lustran/Guardian ABS 348 white 012002 (No 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	Cornerstone	Cornerstone	Cornerstone	Cornerstone
Graduation	Tampapur TPU	Tampapur TPU	Tampapur TPU	Tampapur TPU
Bonding Technology Needle-to-Hub	Directly molded	glued	Directly molded	glued

Characteristics	Subject Device SonoBlock II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Subject Device SonoBlock Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K111374 SonoPlex II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K111374 SonoPlex Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen
Glue	n.a.	(Epoxy adhesive - Araldite 2011), alternatively: UV adhesive (Loctite AA 3921)	n.a.	(Epoxy adhesive - Araldite 2011), alternatively: UV adhesive (Loctite AA 3921)
Injection tube	PVC (MED7536), PC (HP4)	PVC (MED7536), PC (HP4), ABS (Terlux 2802)	PVC (MED7536), PC (HP4)	PVC (MED7536), PC (HP4), ABS (Terlux 2802)
Cable	n.a.	n.a.	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 2mm plug	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 2mm plug
Diameter	20G - 25G	20G - 25G	20G - 25G	20G - 25G
Length	40mm - 120 mm	40mm - 120 mm	40mm - 120 mm	40mm - 120 mm
Connectivity	ISO 80369-6 (NRFit) ISO 80369-7 (LUER)	ISO 80369-6 (NRFit) ISO 80369-7 (LUER)	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	Tyvek, Foil, chromo-duplex board

Characteristics	Subject Device SonoBlock II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Subject Device SonoBlock Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K111374 SonoPlex II Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen	Predicate Device K111374 SonoPlex Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen
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
Sterilization Service Provider	Sterigenics, Wiesbaden HA2 Medizintechnik, Halberstadt	Sterigenics, Wiesbaden HA2 Medizintechnik, Halberstadt	Sterigenics, Wiesbaden	Sterigenics, Wiesbaden
Shelf Life	60 month from sterilization	60 month from sterilization	60 month from sterilization	60 month from sterilization

3 Substantial Equivalence Discussion

The Predicate devices, the SonoPlex 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 SonoBlock 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 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.

4 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

ISO 9626 defines the quality and properties of the stainless steel tubing. The tubing remains unaltered and therefore ongoing compliance with this standard remains unaffected by the change. There is no additional/ new risk of breakage or bending.

ISO 80369-series defines the type of connector which also is not affected by the change. The technical equivalency of LUER and NRFit has been verified and cleared in several submissions before and therefore is in

compliance. The test reports related to this standard series also do not directly contribute to demonstration of substantial equivalence in this submission. There is no additional risk in this regard.

ISO 7864 defines properties of the needle.
Those properties are not directly linked to the material. Section 4.12 of this standard is directly linked to the stability of the connection of the needle and the hub and the risk of detachment oft he needle from the hub. The acceptance criteria have to be met non regarding the material oft he hub and the needle or the type of connection technology. So the test reports for hub-to-needle bondage are required to demonstrate substantial equivalence. The test reports attached to this e-mail subjecting worst case needles demonstrate compliance with the standard (69N required, an average of 104,9N and 196,01N met in result) as well as process stability when manufacturing the needles either with PC Tritan or ABS, either glued or directly moulded.

Needle: stability test bending rigidity
Reason for test: The needle has to demonstrate bending stability and resistance against breakage in order to resist forces reasonably assumed to be applied to the needle in situ under the defined intended use
Procedure of test: The test procedure is defined by international standard EN ISO 9626: Stainless steel needle tubing for manufacture of medical devices.
Acceptance Criteria for bending rigidity/ deflection:

Item code SonoBlock II	Max deflection [mm]	Item code SonoBlock II NRFit®	Max deflection [mm]
001280-71	0,52	001260-74	0,52
001280-74	0,52	001260-89	0,52
001280-77	0,38	001260-71	0,52
001280-95	0,48	001260-77	0,38
001281-71	0,52		
001281-74	0,52		
001281-77	0,38		
001281-72	0,48		
001281-95	0,48		

Item code SonoBlock	Max deflection [mm]	Item code SonoBlock	Max deflection [mm]
001180-77	0,38	001180-31G	0,48
001180-74	0,52		
001180-71	0,52		
001180-81	0,37		
001181-77	0,38		
001181-74	0,52		

Results: The bending rigidity of the subject needles is in compliance with the standard.

Test successfully passed

Needle: Breakage

Reason for test: The needle has to demonstrate stability in order to resist forces reasonably assumed to be applied to the needle in situ under the defined intended use.

Procedure of test: The test procedure is defined by international standard EN ISO 9626: Stainless steel needle tubing for manufacture of medical devices

Acceptance criteria: no breakage during visual inspection after 20 complete cycles of reversal of force at a rate of 0,5 Hz

Test successfully passed

Needle: stability test bonding to hub

Reason for test: The needle has to demonstrate stability at the bonding of the hub in order to resist forces reasonably assumed to be applied to the needle in situ under the defined intended use.

Procedure of test: The test procedure is defined by international standard EN ISO 7864: Sterile hypodermic needles for single use

Acceptance Criteria for bonding to hub:

Item code SonoBlock II	Force min [N]	Item code SonoBlock II NRFit®	Force min [N]
001280-71	40	001260-74	40
001280-74	40	001260-89	40
001280-77	44	001260-71	40
001280-95	54	001260-77	44
001281-71	40		
001281-74	40		
001281-77	44		
001281-72	54		
001281-95	54		

Item code SonoBlock	Force min [N]	Item code SonoBlock	Force min [N]
001180-77	44	001180-31G	40
001180-74	40		
001180-71	40		
001180-81	22		
001181-77	44		
001181-74	40		

Results: The bending rigidity of the subject needles is in compliance with the standard.

Test successfully passed

Needle: Penetration force

Reason for test: The needles have to demonstrate less trauma when applied with the patient under the intended use. ISO 7864 Sterile hypodermic needles for single use recommends penetration force testing only without giving a normative test method.
Procedure of test: According to international European standard EN 13097.
Pass/ Fail criteria: -none- objective comparison only.
Results: The subject needles comply with defined penetration/ insertion forces.

Test successfully passed

Hub/ Connection: Performance tests defined in ISO 80369-20 for compliance with ISO 80369-6 and ISO 80369-7

Reason for test: The hub of the tubing has to demonstrate tightness and stability in order to resist forces reasonably assumed to be applied in situ under the defined intended use.
Procedure of tests: The test procedure is defined by international standard ISO 80369-20 and specific requirements and acceptance criteria are defined in the substandards ISO 80369-6 (for NRFit) and ISO 80369-7 (for LUER)
Tests conducted:
80369-6_6.1_FluidLeakage
80369-6_6.2_AirLeakage
80369-6_6.3_StressCracking
80369-6_6.4_SeparationAxialLoad
80369-6_6.5_Unscrewing
80369-6_6.6_Overriding
80369-7_7.1_FluidLeakage
80369-7_7.2_AirLeakage
80369-7_7.3_StressCracking
80369-7_7.4_SeparationAxialLoad
80369-7_7.5_Unscrewing
80369-7_7.6_Overriding
Results: The subject needles respectively the hubs of the tubes which are part of the needles comply with defined requirements of the standard.

Test successfully passed

5 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

6 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.

7 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.

8 Technology Characteristics

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

9 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}.
Based on current in-process testing regularly conducted, safe performance of the SonoBlock and SonoBlock II needle is demonstrated.