November 22, 2024

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

Re: K241953
Trade/Device Name: SPROTTE® STANDARD (LUER/ NRFit®) Anesthesiology
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: August 29, 2024
Received: August 29, 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)*
K241953

Device Name
SPROTTE® STANDARD (LUER/ NRFit®) Anesthesiology

Indications for Use *(Describe)*
The SPROTTE® STANDARD (LUER/ NRFit®) needles are anesthesia conduction needles which are used to administer anesthetic agent to the subarachnoid space.

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: 2024-11-22

## Document Control Number: K241953

| | |
|---|---|
| **510(k) owner:** | PAJUNK® GmbH Medizintechnologie<br>Karl-Hall-Str. 1/ Pajunkstr. 1<br>78187 Geisingen<br>Baden-Wuerttemberg, Germany<br>Fon: +49(0)7704-9291-586<br>Fax: +49(0)7704-9291-605<br>Establishment Registration Number:<br>**9611612** |
| Submitter Information/ production site: | PAJUNK® GmbH Medizintechnologie<br>Karl-Hall-Str. 1/ Pajunkstr. 1<br>78187 Geisingen<br>Baden-Wuerttemberg, Germany<br>Fon: +49(0)7704-9291-586<br>Fax: +49(0)7704-9291-605<br>Establishment Registration Number:<br>**9611612** |
| **Manufacturer/ Submitter Contact:** | Christian G. H. Quass<br>*Director Regulatory Affairs, Safety Officer*<br>Fon: +49(0)7704-9291-586<br>Fax: +49(0)7704-9291-602<br>E-Mail: christian.quass@pajunk.com |
| **Alternative Manufacturer/ Submitter Contact:** | Chiara Meyer<br>*Regulatory Affairs Specialist*<br>Fon: +49(0)7704-9291-627<br>Fax: +49(0)7704-9291-602<br>E-Mail: chiara.meyer@pajunk.com |
| **USA Contact:** | PAJUNK MEDICAL SYSTEMS<br>4575 Marconi Dr.<br>Alpharetta, GA 30005<br>Registration Number: 3004076349<br>FEI Number*: 3004076349 |

| | |
|---|---|
| **US-Official Correspondent -domestic-** | Marco Wohnig<br>President<br>PAJUNK Medical Systems<br>4575 Marconi Dr.<br>Alpharetta, GA 30005<br>Phone: 001-770-4936832<br>E-Mail: Marco.Wohnig@pajunk-usa.com |
| **US-Official Correspondent -foreign-** | Christian G. H. Quass<br>*Director Regulatory Affairs, Safety Officer*<br>Fon: +49(0)7704-9291-586<br>Fax: +49(0)7704-9291-602<br>E-Mail: christian.quass@pajunk.com |
| Contract Sterilizer: | Sterigenics Germany GmbH<br>Kasteler straße 45<br>65203 Wiesbaden<br>Germany, Hessen<br>Establishment Registration Number: 3002807090 |
| 2nd Contract Sterilizer: | HA2 MEDIZINTECHNIK GMBH<br>Am Bahndamm 11<br>Halberstadt Saxony-Anhalt, DE 38820<br>Registration Number: 3009039068<br>FEI Number*: 3009039068 |

## Device Name and Classification

| | |
|---|---|
| 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<br>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<br>Kasteler straße 45<br>65203 Wiesbaden<br>Germany, Hessen<br>Establishment Registration Number: 3002807090 |
| Additional Contract Sterilizer: | HA2 MEDIZINTECHNIK GMBH<br>Am Bahndamm 11<br>Halberstadt Saxony-Anhalt, DE 38820<br>Registration Number: 3009039068<br>FEI Number*: 3009039068 |

**Changes to Device: Predicate Device**

| | |
|---|---|
| Device Name: | Sprotte NRFit™, Quincke NRFit™ |
| Premarket Notification Number: | K160295 |
| 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<br>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<br>Kasteler straße 45<br>65203 Wiesbaden<br>Germany, Hessen<br>Establishment Registration Number: 3002807090 |

The subject device, the **SPROTTE® STANDARD (LUER/ NRFit®)** needle is a single-use anesthesia conduction needle which is intended to administer anesthetic agent to the subarachnoid space.

The predicate device, the **SPROTTE NRFit, Quincke NRFit** needle is a single-use anesthesia conduction needle which is intended to administer anesthetic agent to the subarachnoid space.

This Premarket Notification is intended to file a standalone 510(k) for the **SPROTTE® STANDARD (LUER/ NRFit®)** 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 **Sprotte NRFit®, Quincke NRFit®** as well as the subject **SPROTTE® STANDARD (LUER/ NRFit®)** are manufactured by PAJUNK GmbH Medizintechnologie, the sponsor of this submission, in Geisingen, Germany.

Both devices, the predicate **Sprotte NRFit®, Quincke NRFit®** as well as the subject **SPROTTE® STANDARD (LUER/ NRFit®)** share the same indications for use.

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.

# 08 510(k) Summary

## 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 subarachnoid 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 sytlet. The cannulas have a LUER hub. The LUER hub is either a standard hub or magnifying. The cannula has a atraumatic, noncutting, symetrical 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 22G-29G. The length has a range from 35mm-150mm. The introducer is optional. It comes in a diameter range from 0,7mm-1,0mm and a length range from 30mm-40mm

**SPROTTE® STANDARD 2.G**
The SPROTTE® cannulas consist of a stainless steel tube, a Tritan hub and are equipped with a sytlet. The cannulas have a LUER hub. The LUER hub is a 2.G hub. The cannula has a atraumatic, noncutting, symetrical pencil point tip with a side-hole opening. The cannula tube is straight.
The SPROTTE® 2.G is designed to increase the speed of the cerebrospinal fluid flow. This would be achieved by the special shape of the cannula interior and the newly designed cannula hub.
The SPROTTE® 2. G is only available with an integrated magnifier.
Even small amounts of cerebrospinal fluid could be identified thanks to the viewing chamber.

The different technical specifications are the the diameter, the length and if it comes with an introducer. The diameter has a range from 22G-27G. The length has a range from 70mm-120mm. The introducer is optional. It comes in a diameter range from 0,7mm-0,8mm 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 sytlet. The cannulas have a NRFit® hub. The NRFit® hub is a magnifying hub. The cannula has a atraumatic, noncutting, symetrical 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 22G-27G. The length has a range from 35mm-200mm. The introducer is optional. It comes in a diameter range from 0,8mm-1,0mm and a length range from 30mm-40mm

# 2 Determination of Substantial Equivalence

**Intended Use Predicate Device (510(K) Predicate)**

The SPROTTE NRFit, Quincke NRFit needles are anaesthesia conduction needles which are used to administer anaestethic agent to subarachnoid space.

**Intended Use Subject Device**

The SPROTTE® STANDARD (LUER/ NRFit®) needles are anesthesia conduction needles which are used to administer anesthetic agent to the subarachnoid space.

**Discussion**

The Intended Use of the Predicate device and of the subject device is substantially equivalent. One device group, the Quincke NRFit needles, have been removed for clarity from this submission.

**Conclusion: substantially equivalent**

# 3 Technical Description

**Substantial Equivalence: Tabulatory Outline**

| Characteristics | Subject Device<br>Sprotte Standard (Luer/ NRFit)<br>Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen | Predicate Device K160295<br>Sprotte NRFit<br>Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen | Predicate Device K160295<br>Quincke NRFit<br>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 | Quincke tip |
| Tip Introducer | Facet tip | Facet tip | n.a. |
| Cannula Hub | PC (Lexan 164R-112)<br>Copolyester (Tritan MX731) | PC (Lexan 164R-112)<br>Copolyester (Tritan MX731) | PC (Lexan 164R-112) |
| Introducer hub | Copolyester (Tritan MX731) | PC (Lexan 164R-112) | n.a. |
| 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 | n.a. |

| | | | |
|---|---|---|---|
| Bonding Technology Needle-to-Hub Cannula | Adhesive bonding | Adhesive bonding | Adhesive bonding |
| Bonding Technology Needle-to-Hub Introducer | Adhesive bonding<br>Overmolding | Adhesive bonding | n.a. |
| Glue Cannula | Epoxy resin (Araldite 2011)<br>UV Adhesive (Dymax 1406-M) | Epoxy resin (Araldite 2011)<br>UV Adhesive (Dymax 1406-M) | Epoxy resin (Araldite 2011) |
| Glue Stylet | Epoxy resin (Araldite 2011) | Epoxy resin (Araldite 2011) | Epoxy resin (Araldite 2011) |
| Glue Introducer | Epoxy resin (Araldite 2011)<br>UV Adhesive (Dymax 1406-M) | Epoxy resin (Araldite 2011) | n.a. |
| Diameter | 22G-29G | 18G-29G | 20G-27G |
| Length | 25-200mm | 50-150 | 50-120mm |
| Connectivity | ISO 80369-6 (NRFit)<br>ISO 80369-7 (LUER) | ISO 80369-6 (NRFit) | ISO 80369-6 (NRFit) |
| Packaging | Tyvek, Foil, chromo-duplex board<br>Alternatively: Paper, Foil | Tyvek, Foil, chromo-duplex board | 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 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 subject device can be either directly injection moulded or glued. The predicate device technology for hub-to-needle bonding is glueing. Both manufacturing technologies are safe and the processes are running stable. Both technologies - direct molding as well as glueing - are standard technologies.

Also the connectivity of the subject device can be eigther LUER or NRFit. The connectivity of the predicate device is NRFit. Both connectivities - 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 either 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.

# 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.

## 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 80369-6 have 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 |

The following sections of the 80369-7 have 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

Efficiancy 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 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.