DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 27, 2016

PAJUNK® GmbH Medizintechnologie
Christian Quass
Director Regulatory Affairs
Karl-hall-str. 1
Geisingen, 78187 DE
Germany

Re: K160295
Trade/Device Name: SPROTTE® NRFit™, Quincke NRFit™
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: September 22, 2016
Received: September 27, 2016

Dear Christian Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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. 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.

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 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160295

Device Name
SPROTTE® NRFit™ and Quincke NRFit™

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

The device is intended for adult and pediatric patients.

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

Date of Preparation: October 27th 2016

Document Control Number: K160295

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Premarket Notification Submission 510(k)

PAJUNK®

Pioneering medical technology

Device Information:

Device Name:	SPROTTE® NRFit™ and Quincke NRFit™
Sterilization method:	Ethylene Oxide disposable device, supplied sterile to the end user and non-sterile intended to be sterilized prior to use to repackagers/ medical device manufacturers
Contract Sterilizer:	Sterigenics Germany GmbH Kasteler straße 45 65203 Wiesbaden Germany, Hessen **Establishment Registration Number:** 3002807090
Document Control 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
Predicate Devices:	K911202 ATRAUMATIC STANDARD SPROTTE NEEDLE (Owner: PAJUNK® GmbH Medizintechnologie) K040965 (Owner: PAJUNK® GmbH Medizintechnologie) PAJUNK TUOHY NEEDLES, QUINCKE NEEDLES, CHIBA NEEDLES & CRAWFORD NEEDLES

PAJUNK® GmbH Medizintechnologie is submitting this *510(k)* for **SPROTTE® NRFit™ and Quincke NRFit™ needles for spinal anaesthesia**.

The intended use as well as the basic technical description 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 these is affected by the altered hub as it is subject to this submission.

12.1 Identification of Predicate devices

In this section SPROTTE® NRFit™ and Quincke NRFit™ needles for spinal anaesthesia are compared to the predicate device.

In order to avoid confusion and to make the information more readable, the predicate devices shall be identified as Predicate Device I (which is for the SPROTTE® NRFit™) and Predicate Device II (which is for the Quincke NRFit™) since the Subject devices are identical in Indications for use while the predicates show differences in wording.

Predicate Device I

The predicate device for the SPROTTE® NRFit™ lumbar puncture needles is:

- K911202 ATRAUMATIC STANDARD SPROTTE NEEDLE (Owner: PAJUNK® GmbH Medizintechnologie)

Predicate Device II

The predicate device for the Quincke NRFit™ lumbar puncture needles is:

- K040965 PAJUNK TUOHY NEEDLES, QUINCKE NEEDLES, CHIBA NEEDLES & CRAWFORD NEEDLES (Owner: PAJUNK® GmbH Medizintechnologie)

12.2 Determination of Substantial Equivalence

12.2.1 Intended Use

Intended Use Subject Device

The SPROTTE® NRFit™, Quincke NRFit™ needles are anesthesia conduction needles which are used to administer anesthetic agent to the subarachnoid space.

Intended Use K911202 (Predicate Device I)

The Standard SPROTTE® Needle is an anesthesia conduction needle which is used to administer anesthetic agent to the subarachnoid space.

Intended Use K040965 (Predicate Device II)

Pajunk's anesthesia conduction needles - Tuohy, Quincke, Chiba, and Crawford - are intended for the transient delivery of anesthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.

Discussion of differences

For the SPROTTE® NRFit™ spinal anaesthesia needles the indications for use is exactly the same as in K911202.

For the Quincke NRFit™ needles for spinal anaesthesia the indication for use is covered by the indications for use as given in the predicate K040965.

Rationale: K040965 covers needles for regional anaesthesia (spinal and epidural) and placement of epidural catheters. In the predicate´s K040965 indications for use instead of the more specific term “subarachnoid” the wider term “regional anaesthesia” is used. So the term used in the subject device´s submission shall be preferred.

Furthermore the predicate device allows placement of a catheter which shall not be covered by the subject device. The Quincke Needle subject to this Premarket Notification is intended for single shot spinal anaesthesia. The anatomical region of the body is absolutely the same. Furthermore Quincke needles (and SPROTTE® needles) are state of the art in spinal puncture for application of anesthetics as well as harvesting spinal fluid. The anatomical regions are absolutely identical.

Conclusion: Substantially Equivalent

The predicate device as well as the subject device only differs in design of the hub. This difference does not have any impact on the performance tests listed below due to the fact, that the materials used, the manufacturing processes employed and the techniques described are absolutely identical.

Technical Description

12.2.2.1 Technical Description SPROTTE

Materials used in SPROTTE® NRFit™ spinal anaesthesia needles:					**Predicate Device**
	NAME OF COMPONENT		**MATERIAL**	**BODY CONTACT**	**MATERIAL K911202**
01	Needle/ cannula	Tubing	Stainless Steel 1.4301 (X5CrNi18-10), AISI 304 (V2A)	Direct, limited	Stainless Steel 1.4301 (X5CrNi18-10), AISI 304 (V2A)
		Hub	Polycarbonate PC	Indirect, limited	Polycarbonate PC
		Optional: Glue	Epoxy resin	No contact at all	Epoxy resin
02	Introducer	Tubing	Stainless Steel 1.4301 (X5CrNi18-10), AISI 304 (V2A)	Direct, limited	Stainless Steel 1.4301 (X5CrNi18-10), AISI 304 (V2A)
		Hub	Polycarbonate PC -	No contact at all	Polycarbonate PC
		Optional: Glue	Epoxy resin	No contact at all	Epoxy resin
03	Stylet	Tubing	Stainless Steel 1.4301 (X5CrNi18-10), AISI 304 (V2A)	Direct, limited	Stainless Steel V2A
		Knob	Polycarbonate PC -	No contact at all	Poliamide
		Optional: Glue	Epoxy resin	No contact at all	Epoxy resin
04	Retaining plate	Plate	Polycarbonate PC -	No contact at all	Polycarbonate GE Lexan 164R
05	Haemostylet	stylet	Stainless Steel 1.4301 (X5CrNi18-10), AISI 304 (V2A)	Direct, limited	Stainless Steel V2A

Based on substantial equivalence testing listed below the following devices are subject to this premarket notification and shall be cleared:

SPROTTE® NRFit™ in a range from 18G to 29G at a rage of length from 50mm to 150mm.

Dimensions intended in the subject devices Premarket Notification K160195:

Length: 50mm to 150mm

Diameter: 18G – 29G

12.2.2.1.1 Discussion of differences

1. The material of the hub has been altered in 1994. Before that date Polycarbonate PC xxx has been used which then was switched to Polycarbonate PC - yyy. The biocompatibility test reports provided for the SPROTTE contain needles equipped with hubs made from yyy. However, the base substance for both is Polycarbonate Medical Grade. xxx has a significant higher flow pattern index.

2. The material of the stylet´s knob has been switched from Poliamide zzz to Polycarbonate PC - yyy. Since the knob does not have any patient contact this change is non-significant to form, fit and function.

12.2.2.2 Technical Description Quincke

Materials used in Quincke NRFit™ spinal anaesthesia needles:					**Predicate Device**
	MATERIAL K190195		**MATERIAL**	**BODY CONTACT**	**MATERIAL K040965**
01	Needle/ cannula	Tubing	Stainless Steel	Direct, limited	Stainless steel
		Hub	Polycarbonate PC -	Indirect, limited	Polycarbonate
		Optional: Glue	Epoxy resin	No contact at all	Epoxy Resin
02	Introducer	Tubing	Stainless Steel	Direct, limited	Stainless steel
		Hub	Polycarbonate PC -	No contact at all	Polycarbonate
		Optional: Glue	Epoxy resin	No contact at all	Epoxy Resin
03	Stylet	Tubing	Stainless Steel	Direct, limited	Stainless steel
		Knob	Polycarbonate PC -	No contact at all	Polycarbonate
		Optional: Glue	Epoxy resin	No contact at all	Epoxy Resin
04	Retaining plate	Plate	Polycarbonate PC	No contact at all	Polycarbonate
05	Fixation Clip	Clip	Polycarbonate PC -	No contact at all	Polycarbonate
05	Haemostylet	stylet	Stainless Steel	Direct, limited	Stainless Steel V2A

Based on substantial equivalence testing listed below the following devices are subject to this premarket notification and shall be cleared:

Quincke NRFit™ in a range from 20G to 27G at a rage of length from 50mm to 120mm.

12.2.2.3 Devices under test

Both, the subject devices as well as the predicate devices have been tested ready to use right after sterilization and have been subject to testing after accelerated aging (1year, 3years, 5years) in order to demonstrate substantial equivalence and Shelf Life.

For demonstrating substantial equivalence the items listed below have been compared:

SPROTTE® NRFfit™

#	Devices/ Materials	Item-number	LOT	*Length [mm]*	Gauge	*sample size*
1	SPROTTE® NRFit™	321163-30F	1116	120	18	15
2	SPROTTE® NRFit™	321163-31C	1116	90	19	15
3	SPROTTE® NRFit™	321163-31B	1116	90	20	15
4	SPROTTE® NRFit™	321163-31A	1116	90	21	15
5	SPROTTE® NRFit™	141163-30C	1116	150	22	15
6	SPROTTE® NRFit™	131163-30A	1116	150	24	15
7	SPROTTE® NRFit™	261163-29A	1116	150	25	15
8	SPROTTE® NRFit™	231163-27A	1116	120	27	15
9	SPROTTE® NRFit™	501163-28A	1116	90	29	15

SPROTTE®

#	Devices/ Materials	Item-number	LOT	*Length [mm]*	Gauge	*sample size*
1	SPROTTE®	321151-30F	1116	120	18	15
2	SPROTTE®	321151-31C	1116	90	19	15
3	SPROTTE®	321151-31B	1116	90	20	15
4	SPROTTE®	321151-31A	1116	90	21	15
5	SPROTTE®	141151-30C	1116	150	22	15
6	SPROTTE®	141151-30A	1116	150	24	15
7	SPROTTE®	061151-29A	1116	150	25	15
8	SPROTTE®	231151-27A	1116	120	27	15
9	SPROTTE®	501151-28A	1116	90	29	15

Quincke NRFit™

#	Devices/ Materials	Item-number	LOT	*Length [mm]*	Gauge	*sample size*
1	Quincke NRFit™	1163-3G080	1116	80	20	15
2	Quincke NRFit™	1163-3E090	1116	90	22	15
3	Quincke NRFit™	1163-7Y090	1116	90	24	15
4	Quincke NRFit™	1163-7C090	1116	90	25	15
5	Quincke NRFit™	1163-7B090	1116	90	27	15

Quincke

#	Devices/ Materials	Item-number	LOT	*Length [mm]*	Gauge	*sample size*
1	Quincke	1149-3G080	1116	80	20	5
2	Quincke	1149-3E090	1116	90	22	5
3	Quincke	1149-7Y090	1116	90	24	5
4	Quincke	1149-7C090	1116	90	25	5
5	Quincke	1149-7B090	1116	90	27	5

12.2.3 Technology/ Performance

12.2.3.1 Performance Testing: Summary

The predicate device as well as the subject device only differs in design of the hub.

This difference does not have any impact on the performance tests listed below. Therefore performance testing is still valid and applies to both, subject device and predicate device.

The performance tests have been accomplished in order to comply with the standards listed below (even though 6-366 and 6-362 are not directly linked with Product Code BSP):

Recognition-#	Standard Number	Title
6-366	ISO 9626	Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
6-362	ISO 7864	Sterile hypodermic needles for single use - Requirements and test methods
5-108	ISO 80369-6	Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications.

Stability test Bonding-to-Hub has to be conducted in order to compare the stability of the LUER Hub with the stability of the NRFit™ hub.

Furthermore compliance of the needle hub with ISO 80369-6 has to be proven.

Standard testing regarding the remaining sections of the recognized performance standards can be conducted using either the predicate device or the subject device because the needle tubing is absolutely identical.

<u>Needle: stability test bending rigidity</u>

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 ISO/FDIS 9626:2016 Stainless steel needle tubing for manufacture of medical devices.

Pass/ Fail criteria: The acceptance criterion of bending rigidity for the cannula is defined in above mentioned standard.

Results: The bending rigidity of the predicate device´s needles and the subject device´s needles is compliant with the standard.

Conclusion: Substantially Equivalent

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 ISO/FDIS 7864:2016 Sterile hypodermic needles for single use

Pass/ Fail criteria: The acceptance criterion for the bond between hub and needle tube (pull-off force) is ≥22N.
Results: For the needles of the subject device and the needles of the predicate device a force significantly higher than the target value has to be applied. Therefore the predicate device´s needles as well as the subject device´s needles are substantially equivalent.

Conclusion: Substantially Equivalent

Needle: Penetration force

Reason for test: The needles have to demonstrate less trauma when applied with the patient under the intended use. ISO/FDIS 7864:2016 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 device´s needles as well as the predicate device´s needles show identical penetration/ insertion forces.

Conclusion: Substantially Equivalent

2.3.2 Performance Testing: Comparison of test reports

2.3.2.1 7864_9626_5.8_Stiffness

All tests are passed successfully. There are no significant differences between the baseline and the aged needles nor are there significant differences between the predicate device and the subject device.

Compliance to this section of the standard and Shelf life of 5 years is proven.

Substantial Equivalence is demonstrated.

12.2.3.2.2 7864_4.10_Penetration_

All tests are passed successfully. There are no significant differences between the baseline and the aged needles nor are there significant differences between the predicate device and the subject device.

Compliance to this section of the standard and Shelf life of 5 years is proven.

Substantial Equivalence is demonstrated.

12.2.3.2.3 7864_4.11_Hub-To-Needle_

All tests are passed successfully. There are no significant differences between the baseline and the aged needles nor are there significant differences between the predicate device and the subject device.

Compliance to this section of the standard and Shelf life of 5 years is proven.

Substantial Equivalence is demonstrated.

2.3.2.4 _9626_5.9_Breakage_

This section summarizes the results of standard testing for the SPROTTE® NRFit™ and SPROTTE according to ISO/ FDIS 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods Clause 5.9 Resistance to breakage

All tests are passed successfully. There are no significant differences between the baseline and the aged needles nor are there significant differences between the predicate device and the subject device.

Compliance to this section of the standard and Shelf life of 5 years is proven.

Substantial Equivalence is demonstrated.

2.4 Sterilization

The predicate device as well as the subject device only differs in design of the hub. This difference does not have any impact on Sterilization. Therefore the Sterilization validation is still valid.

The contract sterilizer and the sterilizing process are identical to the contract sterilizer and the sterilizing process 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%
Exposure time	300 min.
Aeration method	evacuation 2 airwashes
Aeration period	residual EtO-gas is removed in circulating air at 40° C (±5) for at least 48h

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 the rabbit pyrogen test) and EtO-residuals as well as shelf life have been validated.

The limits listed below are met by each device:

The needles are also available in bulk non sterile. If appropriately packed and sterilized with Ethyleneoxide according to the parameters above the technological parameters remain unchanged. However, final responsibility for sterilization validation remains with the customer of needles purchased bulk non-sterile.

2.5 Shelf Life

The predicate device as well as the subject device only differs in design of the hub. This difference does not have any impact on Shelf Life. Therefore the Shelf Life is still valid.

Efficacy of sterile product´s lifecycle has been validated using similar products and worst case devices.

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

Performance of the essential performance of the device (LUER/ NRFit™ connection, stability of bonding connections, catheter´s tensile strength, needle´s bending rigidity) has been tested with real time aged needles and catheters made from identical material employing identical processes and those are found to work properly. There is no decrease in performance after 5 years.

Shelf-life is set to 5 years.

2.6 Biocompatibility:

The predicate device as well as the subject device only differs in design of the hub. The manufacturing processes of the subject device and the predicate device are identical. The difference in design does not have any impact on Biocompatibility of the device. Therefore the biocompatibility testing conducted with the predicate device is still valid.

All devices comply with ISO 10993-1, 2nd and 3rd edition.

The components of the SPROTTE® NRFit™ and Quincke NRFit™ are identical to the components of the SPROTTE and Quincke as they were approved/cleared in K911202 and K040965 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

The components of the subject devices SPROTTE® NRFit™ and Quincke NRFit™ and the components of the predicate devices SPROTTE and Quincke are identical to the components of the worst case device which has been tested in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

The tests listed below have been conducted and accomplished successfully by the worst case device:

- *In vitro* Cytotoxicity_ISO 10993-5
- Irritation_ISO 10993-10
- Sensitization ISO 10993-10
- Acute systemic toxicity
- Hemocompatibility

Therefore and based upon sterilization validation and residuals validation the devices are considered to be biocompatible.

3. Conclusion

All tests are passed successfully. There are no significant differences between the baseline and the aged needles Subject device and Predicate device nor are there significant differences between the predicate device and the subject device in performance.

Compliance to international standards and Shelf life of 5 years is proven.

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified.