DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 27, 2016

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

Re: K160296
Trade/Device Name: SPROTTE® Special 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.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160296

Device Name
SPROTTE® Special NRFit™

Indications for Use *(Describe)*
The SPROTTE® SPECIAL NRFit™ anaesthesia conduction needle is intended to gain entry into the spinal canal to apply single shot spinal anaesthesia. It has an opening which will allow the introduction of a catheter which is used to inject anaesthetics to provide continuous spinal anaesthesia.

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.

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
PRAStaff@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."

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

Date of Preparation: October 27th 2016

Document Control Number: K160296

510(k) owner:
PAJUNK® GmbH Medizintechnologie
Karl-Hall-Str. 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
78187 Geisingen
Baden-Wuerttemberg, Germany
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
Establishment Registration Number:
9611612

USA Contact:
PAJUNK MEDICAL SYSTEMS
6611 Bay Circle, Suite 140
Norcross, GA 30071
Phone +1 (888) 9PAJUNK (72-5865)
Fax +1 (678) 514-3388

Establishment Registration Number:
3004076349

Contact:
Christian G. H. Quass
Director Regulatory Affairs, Safety Officer
Patricia Weisbrod
Regulatory Affairs Manager
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
E-Mail: christian.quass@pajunk.com
E-Mail: patricia.weisbrod@pajunk.com

Contact
Marco Wohnig
President
PAJUNK® Medical Systems L.P.
Phone: (770) 493-6832
Direct: (470) 448-4070
Cell: (770) 757-2449
Fax: (678) 514-3388
E-Mail: marco.wohnig@pajunk-usa.com

Premarket Notification Submission 510(k)

PAJUNK®
Pioneering medical technology

Device Information:

Device Name:	SPROTTE® Special 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	*K160296*
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:	K911221 ATRAUMATIC SPECIAL SPROTTE NEEDLE Owner: PAJUNK® GmbH Medizintechnologie

PAJUNK® GmbH Medizintechnologie is submitting this *510(k)* for **SPROTTE® Special 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.

Predicate Device

The predicate device for the SPROTTE® SPECIAL NRFit™ Anaesthesia conduction needle is:

- K911221 ATRAUMATIC SPECIAL SPROTTE NEEDLE (Owner: PAJUNK® GmbH Medizintechnologie)

12.2 Determination of Substantial Equivalence

12.2.1 Intended Use

Intended Use Subject Device

The SPROTTE® SPECIAL NRFit™ anaesthesia conduction needle is intended to gain entry into the spinal canal to apply single shot spinal anaesthesia. It has an opening which will allow the introduction of a catheter which is used to inject anaesthetics to provide continuous spinal anaesthesia.

Intended Use K911221 (Predicate Device)

This needle is intended to gain entry into the spinal canal. It has an opening which will allow the introduction of a catheter which is used to inject anaesthetics to provide continuous spinal anaesthesia.

Discussion of differences

For the SPROTTE® SPECIAL NRFit™ needle the indications for use is exactly the same as for the predicate device.

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.

12.2.2 Technical Description

12.2.2.1 Technical Description SPROTTE Special

Materials used in SPROTTE® Special NRFit™ spinal anaesthesia needles:					Predicate Device
	NAME OF COMPONENT		MATERIAL	BODY CONTACT	MATERIAL K911221
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
		Ramp in tip	Polycarbonate PC -	Indirect, limited	Epoxy resin
		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 U
04	Retaining plate	Plate	Polycarbonate PC -	No contact at all	Polycarbonate
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® Special NRFit™ in a range from 18G to 24G at a rage of length from 90mm to 100mm.

Dimensions cleared in Predicate Device´s Premarket Notification 510(k): K911221

Length: 90mm -103mm

Diameter: 22G – 24G

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.

12.2.2.3 Devices under test

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

Subject devices under test

#	Devices/ Materials	Item-number	LOT	*Length [mm]*	Gauge
1	SPROTTE® Special NRFit™	0011163-54	1116	90	18
2	SPROTTE® Special NRFit™	0001163-54	1116	90	19
3	SPROTTE® Special NRFit™	0051163-55	1116	100	21
4	SPROTTE® Special NRFit™	0061163-55	1116	100	22
5	SPROTTE® Special NRFit™	0071163-54	1116	90	24

Predicate devices under test

#	Devices/ Materials	Item-number	LOT	*Length [mm]*	Gauge
1	SPROTTE® Special	0011151-54	1116	90	18
2	SPROTTE® Special	0001151-54	1116	90	19
3	SPROTTE® Special	0051151-55	1116	100	21
4	SPROTTE® Special	0061151-54	1116	100	22
5	SPROTTE® Special	0071151-54	1116	90	24

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.

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

2.4 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 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.