DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 28, 2016

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

Re: K160297
Trade/Device Name: Tuohy NRFit™
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: September 23, 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)*
K160297

Device Name
Tuohy NRFit™

Indications for Use *(Describe)*
The Tuohy NRFit™ cannulas/ needles for anesthesia and analgesia are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of an epidural catheter.

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: September 23, 2016

Document Control Number: **K160297**

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Device Information:

Device Name:	Tuohy 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	*K160297*
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:	K040965 (Owner: PAJUNK® GmbH Medizintechnologie) PAJUNK TUOHY NEEDLES, QUINCKE NEEDLES, CHIBA NEEDLES & CRAWFORD NEEDLES

PAJUNK® GmbH Medizintechnologie is submitting this Premarket Notification according to *510(k)* for Tuohy NRFit™ Anaesthesia conduction needles.

The intended use as well as the basic technical description of the needle which is relevant to clinical use is identical to the predicate device and has been cleared in 510(k)s sent in earlier by the sponsor.

The only difference between the predicate device and the subject device is the design of the needle´s hub. While the predicate devices are equipped with a LUER taper connector the subject devices are equipped with a NRFit connector as it is described in ISO 80369-6 for neuroaxial devices.

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 absolutely identical. None of these is affected by the altered hub as it is subject to this submission.

Indications for use subject device:

The Tuohy NRFit™ cannulas/ needles for anesthesia and analgesia are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of an epidural catheter. The device is intended for adult and pediatric patients.

Device Description:

The Tuohy NRFit™ anaesthesia conduction needles are available in different sizes (length and diameter). Optional Accessories are retaining plate and stylet made from plastic or stainless steel as it has been cleared in the predicate device´s 510(k)s.

The Tuohy NRFit™ anaesthesia conduction needles can be used for both, epidural anaesthesia and peripheral nerve blocks each equipped with appropriate labelling as the Tuohy needle in general is a commonly used needle with both clinical demands and techniques.

12.1 Identification of Predicate devices

The Tuohy NRFit™ cannulas/ needles for anesthesia and analgesia are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of a catheter.

Predicate Device

The predicate device for the Tuohy NRFit™ anaesthesia conduction needles is:

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

12.2 Determination of Substantial Equivalence

12.2.1 Intended Use

Intended Use Subject Device

The Tuohy NRFit™ cannulas/ needles for anesthesia and analgesia are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of an epidural catheter.

Intended Use K040965 Predicate Device

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.

Conclusion: Substantially Equivalent

12.2.2 Technical Description

12.2.2.1 Technical Description Tuohy and Tuohy NRFit™

Materials used in Tuohy NRFit™ anaesthesia conduction needles:					Predicate Device
	MATERIAL K911221		MATERIAL	BODY CONTACT	MATERIAL K040965
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
03	Stylet (Subcomponent)	Tubing	Stainless Steel 1.4301 (X5CrNi18-10), AISI 304 (V2A)	Direct, limited	Stainless Steel 1.4301 (X5CrNi18-10), AISI 304 (V2A) or Polyamide
		knob	Polycarbonate PC -	Indirect, limited	Polycarbonate PC -
		Glue	Epoxy resin	No contact at all	Epoxy resin
04	Retaining plate (Subcomponent)	Plate	Polycarbonate PC -	No contact at all	Polycarbonate PC -

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

Tuohy NRFit™ in a range from 14G to 22G at a rage of length from 90mm to 150mm.

12.2.2.1.1 Discussion of differences

There are no differences besides the hub connector between the predicate device and the subject device.

In order to define regional anesthesia more precise, the Tuohy NRFit™ cannulas/ needles for anesthesia and analgesia shall be cleared for epidural and peripheral use.

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	*Length [mm]*	Gauge
1	Tuohy NRFit™	1166-4T100	100	14
2	Tuohy NRFit™	1166-4O150	150	16
3	Tuohy NRFit™	1166-4M090	90	17
4	Tuohy NRFit™	1166-4K090	90	18
5	Tuohy NRFit™	1166-4I090	90	19
6	Tuohy NRFit™	1166-4G090	90	20
7	Tuohy NRFit™	1166-4F090	90	21
8	Tuohy NRFit™	1166-4E090	90	22

Predicate devices under test

#	Devices/ Materials	Item-number	*Length [mm]*	Gauge
1	Tuohy	1150-4T100	100	14
2	Tuohy	1150-4O150	150	16
3	Tuohy	1150-4M090	90	17
4	Tuohy	1150-4K090	90	18
5	Tuohy	1150-4I090	90	19
6	Tuohy	1150-4G090	90	20
7	Tuohy	1150-4F090	90	21
8	Tuohy	1150-4E090	90	22

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.

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:

Limits for Residuals: 25ppm = 25µg/(g/device) of Ethyleneoxide (EO); 25ppm = 25µg/(g/device) Ethylene chlorhydrine

Limit for Pyroburden/ endotoxine: 0,06 EU/ml and 2,15 EU/ device acc. to FDA GUIDELINE ON VALIDATION OF LIMULUS AMEBOCYTE LYSATE TEST AS AN END-PRODUCT ENDOTOXIN TEST FOR HUMAN AND ANIMAL PARENTERAL DRUGS, BIOLOGICAL PRODUCTS, AND MEDICAL DEVICES – Issued 12/ 1987

The needles are also available in bulk non sterile. If appropriately packed and sterilized with Ethylene oxide 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.

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.

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.

Shelf-life is set to 5 years (60 month).

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 because the materials used as well as the processes employed (glue or/and direct injection moulding) remain unaltered. Therefore the biocompatibility testing conducted with the predicate device is still valid.

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

According to Table A.1 of Attachment A of this guidance the Tuohy NRFit™ needles, subject to this submission, have been identified as

- External communicating device
- Blood Path, indirect
- Limited (<24h)

The FDA-recommended tests are:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatibility

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

Technology Characteristics:

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.

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 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

Conclusion:

The comparison between the predicate devices and the subject device of this submission as well as the validated sterilization process and the results of the standard testing, bench testing and bench marking demonstrates that the subject devices are substantially equivalent to the predicate devices and substantially equivalent in technical description to devices already cleared for market and therefore demonstrated to be as safe and effective as the legal predicate devices. Actually besides the design of the hub (Subject Device: NRFit™, Predicate Device: LUER) the devices are identical.

Based on the rationale provided above and additionally conducted dimension compliance testing for the ISO 80369-6 NRFit™ hub, acceptable performance was demonstrated for Tuohy NRFit™ anaesthesia conduction needles.