June 17, 2019

PAJUNK GmbH Medizintechnologie
Christian Quass
Director Regulatory Affairs, Safety Officer
Karl-Hall-Str. 1
78187 Geisingen,
Baden-Wuerttemberg, Germany

Re: K190663
Trade/Device Name: Epidural MiniFilter LUER (ISO80369-7), Epidural MiniFilter NRFit (ISO80369-6)
Regulation Number: 21 CFR 868.5130
Regulation Name: Anesthesia Conduction Filter
Regulatory Class: Class II
Product Code: BSN
Dated: May 17, 2019
Received: May 20, 2019

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190663

Device Name
Epidural MiniFilter
NRFit (ISO80369-6) and LUER (ISO80369-7)

Indications for Use *(Describe)*
The Pajunk Epidural MiniFilter NRFit (ISO80369-6) and Epidural MiniFilter LUER (ISO80369-7) is an anesthesia conduction filter. An anesthesia conduction filter is a microporous filter used while administering to a patient injection of local anaesthetics to minimize particulate (foreign material) contamination of the injected fluid. The anaesthesia conduction filter is intended for use for patients that weigh 10kg and above.

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: 2019-06-17

Document Control Number: K190663

510(k) owner:

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Establishment Registration Number: **9611612**

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Device Information:

Device Name:	Epidural MiniFilter NRFit™ (ISO80369-6) Epidural MiniFilter LUER (ISO80369-7)
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	**K190663**
Classification Name:	**filter, conduction, anesthetic**
Classification Reference:	21 CFR 868.5130
Product Code:	BSN
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology
Predicate Device	K083451, Portex® Epidural Filter

PAJUNK® GmbH Medizintechnologie is submitting this 510(k) for 2 types of Anaesthesia Conduction Filter called Epidural MiniFilter with either NRFit™ Connector according to ISO 80369-6 or LUER-Connector according to ISO 80369-7. The types only differ in shape of the hub.

The Filter is a Class II medical device substantially equivalent to the predicate device (K083451, Portex Epidural Filter) as defined in 21 CFR §868.5130, product code BSN

The device is a sterile finished disposable device, supplied sterile to the end user and non-sterile intended to be sterilized prior to use to re-packagers/ medical device manufacturers.

The predicate device chosen for demonstrating substantial equivalence is the Portex Epidural Filter manufactured by SMITHS MEDICAL ASD, INC., 10 bowman dr., keene, NH 03431 and cleared by the Food and Drug Administration for market under K083451, product code BSN, review panel Anaesthesiology.

Indications for use

The Pajunk Epidural MiniFilter NRFit™ (ISO80369-6) and Epidural MiniFilter LUER (ISO80369-7) is an anesthesia conduction filter. An anesthesia conduction filter is a microporous filter used while administering to a patient injection of local anaesthetics to minimize particulate (foreign material) contamination of the injected fluid. The anaesthesia conduction filter is intended for use for patients that weigh 10kg and above.

Determination methods and results of Substantial Equivalence Determination:

Intended Use	Result: Substantially Equivalent
Design	Result: Substantially Equivalent
Performance	Result: Substantially Equivalent

Equivalence in materials used

Characteristics	**Predicate device** **K083451**	**Subject Device** **Anaesthesia Conduction Filter**	***Result of comparison, if necessary with rationale***
Biocompatibility	Both devices are classified as externally communicating. Therefore and based upon ISO10993-1 biocompatibility applies.		Substantially equivalent
Packaging	Individually sterile in soft blister pouch or as part of a kit	Individually sterile in soft blister pouch or as part of a kit	Same packaging The PAJUNK® individual packaging was selected according to a validated sterilization and transportation process
Indications for Use	An anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.	The Pajunk Epidural MiniFilter NRFit™ (ISO80369-6) and Epidural MiniFilter LUER (ISO80369-7) is an anesthesia conduction filter. An anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.	Substantially equivalent
Overall design:	Round, flat housing Female Lock and male connector with rotating locking hub Filter membrane	flat housing Female Lock and male connector with rotating locking hub Filter membrane	identical Both devices do not have direct patient contact and are made from plastic materials

Characteristics	Predicate device K083451	Subject Device Anaesthesia Conduction Filter	*Result of comparison, if necessary with rationale*
Picture			Both systems allow easy handling and connecting
Materials used	Filter housing: Modified Acrylic Filter Media: Supor® 200- 0.2µm (PES)	Filter housing: Modified Acrylic Filter Media: Hydrophilic HI-FLO PES membrane 0.2µm	identical Each of the materials used either in the Predicate Devices or the Subject Device are established materials used for manufacturing medical devices.
Connectivity	ISO 80369-7	ISO 80369-6 NRFit™ ISO 80369-7 LUER	Both systems do have identical connectivity towards syringe and needle; 2017´s state of the art connection type is NRFit™ which slightly differs in dimensions of the male and female connectors in order to avoid misconnections.
Filtration Area	5,25cm^2	1,45cm^2	Due to smaller size the subject devices filtration area is smaller. The filtration properties i. e. the intended use are not affected by this difference.
Flow Rate	≥ 200ml/Min	≥ 200ml/Min	identical
Bubble Point	≥ 46psi.	≥ 46psi.	identical

Equivalence in the Indications for use

Subject Device:

The Pajunk Epidural MiniFilter NRFit™ (ISO80369-6) and Epidural MiniFilter LUER (ISO80369-7) is an anesthesia conduction filter. An anesthesia conduction filter is a microporous filter used while administering to a patient injection of local anaesthetics to minimize particulate (foreign material) contamination of the injected fluid.

Predicate Devices:

An anesthesia conduction filter is a microporous filter used while administering to a patient injection of local anaesthetics to minimize particulate (foreign material) contamination of the injected fluid.

Discussion

The indications for use as well as the intended use of the predicate devices and of the subject device are identical. Pajunk´s IFU statement is amended by an introducing statement of identity identifying the tradenames for the common term “anaesthesia conduction filter”.

Conclusion: Substantially Equivalent

Sterilization

Subject Device:

Sterilized with Ethylene Oxide. Shelf Life: 5 years.

Predicate Devices:

Sterilized with Ethylene Oxide. Shelf Life: 5 years.

Discussion

Both devices are sterilized using Ethylene Oxide and have a shelf life of 5 years.

Conclusion: Substantially Equivalent

Performance Testing

Subject Device:

Connectivity: LUER and NRFit™ (ISO 80369-6 and ISO 80369-7).

Leak Tightness: Complies with internal protocol

Flow Rate: Complies with internal protocol

Burst Pressure: Complies with internal protocol

Bubble Point: Complies with internal protocol

Predicate Devices:

Connectivity: LUER (ISO594/ ISO80369-7).

Leak Tightness: Complies with internal protocol of the sponsor

Flow Rate: Complies with internal protocol of the sponsor

Burst Pressure: Complies with internal protocol of the sponsor

Bubble Point: Complies with internal protocol of the sponsor

Technology Characteristics/ Performance Testing

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%
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 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 of Ehyleneoxide and Ethylene chlorhydrine are met.

Limit for Pyroburden/ endotoxine is met.

The filters 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 filters purchased bulk non-sterile.

Shelf Life

Efficacy of sterile product´s lifecycle has been validated.

Sterility tests have been performed. Performance of the essential performance of the device (NRFit and LUER connection, stability of connections) has been tested with real time aged devices (1 year) and devices subject to accelerated aging (1 year, 3 years, 5 years). There is no decrease in performance after 5 years.

Shelf-life is set to 5 years.

Biocompatibility:

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

The Subject Device is an external communicating device with no direct patient contact. Therefore based upon ISO10993-1 biocompatibility is evaluated and tested.

Biocompatibility has been evaluated and tested according to ISO 10993-1. The tests conducted are testing for Cytotoxicity according to ISO10993-5 and Chemical Analysis and Evaluation according to ISO10993-12. The evaluation and qualification method complies with ISO10993-1 as well as with FDA-2013-D-0350 “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

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

Standards/ Requirements

The Subject Device has been tested to comply with the state-of-the-art standards listed below. For connector standards both, the male and female connectors have been tested:

Test Detail	Standard	FDA-Rec.-No.	Result
Sterilization	ISO 11135	14-452	Pass
Residuals	ISO 10993-7	14-408	Pass
Biocompatibility	ISO 10993-1	2-220	Pass
Liquid Leakage	ISO 80369-7, 6.1	5-115	Pass
Air Leakage	ISO 80369-7, 6.2	5-115	Pass
Stress Cracking	ISO 80369-7, 6.3	5-115	Pass
Axial Load	ISO 80369-7, 6.4	5-115	Pass
Unscrewing torque	ISO 80369-7, 6.5	5-115	Pass
Overriding	ISO 80369-7, 6.6	5-115	Pass

Test Detail	Standard	FDA-Rec.-No.	Result
Liquid Leakage	ISO 80369-6, 6.1	5-108	Pass
Air Leakage	ISO 80369-6, 6.2	5-108	Pass
Stress Cracking	ISO 80369-6, 6.3	5-108	Pass
Axial Load	ISO 80369-6, 6.4	5-108	Pass
Unscrewing torque	ISO 80369-6, 6.5	5-108	Pass
Overriding	ISO 80369-6, 6.6	5-108	Pass
Burst Pressure	Internal protocol	n.a.	Pass
Bubble Point	Internal Protocol	n.a.	Pass
Leak Tightness	Internal Protocol	n.a.	Pass
Flow Rate	Internal Protocol	n.a.	Pass
ISTA Procedure 2A (ASTM D 6653 et al.)			
ASTM F1886 - 09			
ASTM F 1929 – 98			
ASTM E 515 – 05 (4a))			
DIN EN 868-5:2009-09			
DIN EN 868-10:2009-09			

Conclusion:

The comparison between the predicate device and the subject device, as well as the validated sterilization process and the results of the standard testing and performance testing demonstrates that the subject device is substantially equivalent to the predicate device. The subject device is safe and effective as the legally marketed predicate device.