Pajunk GmbH Medizintechnologie
Christian Quass
Director Regulatory Affairs
Karl-Hall-Str. 1
Geisingen, 78187 De

Re: K190345
Trade/Device Name: VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7)
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: Class II
Product Code: CAZ
Dated: April 16, 2019
Received: April 19, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael Ryan
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190345

Device Name
VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7)

Indications for Use *(Describe)*
Indication for Use: The VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7) Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use.
The loss of Resistance Syringe is not intended for injection or aspiration.
The Syringe will be sold sterile individually packaged, and as part of a sterile kit.

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: 2019-05-16

Document Control Number: K190345

510(k) owner:

PAJUNK® GmbH Medizintechnologie
Karl-Hall-Str. 1
78187 Geisingen, Baden-Wuerttemberg, Germany

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

Device Information:

Device Name:	VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and 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	**K190345**
Classification Name:	**conduction, anesthetic**
Classification Reference:	21 CFR 868.5140
Product Code:	CAZ
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology
Predicate Device	K061737, Busse Loss of Resistance Syringe

PAJUNK® GmbH Medizintechnologie is submitting this 510(k) for the *VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7)* for identification of loss of resistance prior to epidural anaesthesia procedures with either NRFit™ Connector according to ISO80369-6 or LUER-Connector according to ISO80369-7.

The VPC is considered a Class II medical device according to the predicate device as defined in 21 CFR §868.5140, product code CAZ.

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 devices chosen for demonstrating substantial equivalence is the **Busse Loss of Resistance Syringe** manufactured by **ROBERT BUSSE & CO., INC. P.O. BOX 11067 Hauppauge, NY 11788** and cleared by the Food and Drug Administration for market under **K061737**, product code **CAZ**, review panel Anaesthesiology.

Indications for use

Indication for Use: The VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7) Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use.

The loss of Resistance Syringe is not intended for injection or aspiration.

The Syringe will be sold sterile individually packaged, and as part of a sterile kit.

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** **Busse LOR Syringe** **K061737**	**Subject Device** **VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7) Loss of Resistance Syringe**	***Result of comparison, if necessary with rationale***
Biocompatibility	Both devices are classified as externally communicating. Therefore, 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	Indication for Use: The Busse Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of Resistance Syringe is not intended for injection or aspiration. The Syringe will be sold sterile individually packaged, and as part of a sterile kit.	Indication for Use: The VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7) Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use. The loss of Resistance Syringe is not intended for injection or aspiration. The Syringe will be sold sterile individually packaged, and as part of a sterile kit.	identical
Overall design:	Barrel, Plunger	Barrel, plunger	identical Both devices do not have direct patient contact and are made from plastic materials

Characteristics	**Predicate device** **Busse LOR Syringe** **K061737**	**Subject Device** **VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7) Loss of Resistance Syringe**	***Result of comparison, if necessary with rationale***
Picture			Both systems allow easy handling and connecting and have a smooth plunger for LOR-technique
Materials used	Plastic materials	Plastic materials	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.
Markings Area	0ml – 10ml	0ml – 10ml	identical
Priming Volume	10ml	10ml	identical

Equivalence in the Indications for use

Subject Device:

Indication for Use: The VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7) Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use.

The loss of Resistance Syringe is not intended for injection or aspiration. The Syringe will be sold sterile individually packaged, and as part of a sterile kit.

Predicate Devices:

Indication for Use: The Busse Loss of Resistance Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the loss of Resistance technique, it will be filled with air and/or saline during use.

The loss of Resistance Syringe is not intended for injection or aspiration. The Syringe will be sold sterile individually packaged, and as part of a sterile kit.

Discussion

The indications for use as well as the intended use of the predicate devices and of the subject device are identical.

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).

Stability of markings: Complies with internal protocol

Stability of connectivity during Shelf Life: LUER and NRFit™ (ISO 80369-6 and ISO 80369-7).

Identification of LOR: Complies with internal protocol

Identification of LOR during Shelf Life: Complies with internal protocol

Predicate Devices:

Stability of markings: Complies with internal protocol

Identification of LOR: Complies with internal protocol

Technology Characteristics/ Performance Testing

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 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 Ethylene oxide and Ethylene chlorohydrin are met.

Limit for Pyrogen/ endotoxin is met.

The VPC is 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 VPC 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.

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
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
Stability of markings	Internal protocol	n.a.	Pass
Identification of LOR	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			

Test Detail	Standard	FDA-Rec.-No.	Result
DIN EN 868-10:2009-09			

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 and performance testing demonstrates that the subject device is substantially equivalent to the predicate device without raising different questions of safety and effectiveness.

Device: VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7) Loss of Resistance Syringe			
Test Detail	**Standard**	**Level**	**Result**
Liquid Leakage	ISO 80369-7, 6.1	3 years accelerated aging	Pass
Air Leakage	ISO 80369-7, 6.2	3 years accelerated aging	Pass
Stress Cracking	ISO 80369-7, 6.3	3 years accelerated aging	Pass
Axial Load	ISO 80369-7, 6.4	3 years accelerated aging	Pass
Unscrewing torque	ISO 80369-7, 6.5	3 years accelerated aging	Pass
Overriding	ISO 80369-7, 6.6	3 years accelerated aging	Pass
LOR	Internal protocol	3 years accelerated aging	Pass
Tightness	Internal Protocol	3 years accelerated aging	Pass
Stability Markings	Internal Protocol	3 years accelerated aging	Pass

Device: VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7) Loss of Resistance Syringe			
Test Detail	**Standard**	**Level**	**Result**
Liquid Leakage	ISO 80369-7, 6.1	5 years accelerated aging	Pass
Air Leakage	ISO 80369-7, 6.2	5 years accelerated aging	Pass
Stress Cracking	ISO 80369-7, 6.3	5 years accelerated aging	Pass
Axial Load	ISO 80369-7, 6.4	5 years accelerated aging	Pass
Unscrewing torque	ISO 80369-7, 6.5	5 years accelerated aging	Pass
Overriding	ISO 80369-7, 6.6	5 years accelerated aging	Pass
LOR	Internal protocol	5 years accelerated aging	Pass
Tightness	Internal Protocol	5 years accelerated aging	Pass
Stability Markings	Internal Protocol	5 years accelerated aging	Pass

Device: VPC (Visual Pressure Control) NRFit™ (ISO80369-6) and LUER (ISO80369-7) Loss of Resistance Syringe			
Test Detail	**Standard**	**Level**	**Result**
Liquid Leakage	ISO 80369-7, 6.1	1 year real time aging	Pass
Air Leakage	ISO 80369-7, 6.2	1 year real time aging	Pass
Stress Cracking	ISO 80369-7, 6.3	1 year real time aging	Pass
Axial Load	ISO 80369-7, 6.4	1 year real time aging	Pass
Unscrewing torque	ISO 80369-7, 6.5	1 year real time aging	Pass
Overriding	ISO 80369-7, 6.6	1 year real time aging	Pass
LOR	Internal protocol	1 year real time aging	Pass
Tightness	Internal Protocol	1 year real time aging	Pass
Stability Markings	Internal Protocol	1 year real time aging	Pass