DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 12, 2017

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

Re: K170435
Trade/Device Name: NerveGuard NRFit, NerveGuard LUER
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP, CAZ
Dated: June 14, 2017
Received: June 16, 2017

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,

Mark S. Fellman -S

for Lori A. Wiggins, MPT, CLT
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)*
K170435

Device Name
NerveGuard NRFit
NerveGuard LUER

Indications for Use *(Describe)*
The NerveGuard Nerve Block Injection Pressure Limiter is a disposable manometer for measuring injection pressure during administration of peripheral nerve blocks.

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: 2017-07-12

Document Control Number: *K170435*

510(k) owner:

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Establishment Registration Number: **9611612**

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Device Information:

Device Name:	**NerveGuard NRFit** **NerveGuard LUER**
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	**K170435**
Classification Name:	Anesthetic conduction needle
Classification Reference:	21 CFR 868.5150
Product Codes:	BSP, CAZ
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology
Predicate Device by competitor	K031128 B-Smart

PAJUNK® GmbH Medizintechnologie is submitting this 510(k) for the NerveGuard with either NRFit Connector according to ISO80369-6 or LUER-Connector according to ISO80369-7.

Substantial equivalence is based on a competitor´s device.

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 repackagers/ medical device manufacturers.

Indications for use

The NerveGuard Nerve Block Injection Pressure Limiter is a disposable manometer for measuring injection pressure during administration of peripheral nerve blocks.

Device Description/ Principle of operation

The NerveGuard NRFit and NerveGuard LUER are single use sterile devices.

The NerveGuard NRFit and NerveGuard LUER are packed in a soft blister package.

The procedure requires connection to a needle intended for peripheral neve block and an injection device, typically a 10/20ml syringe (not subject to this 510(k)).

The NerveGuard is attached between the hub of the needle and the syringe via male and female connector.

Upon starting injection the pressure is monitored while the needle is inserted into the patients´ skin. When exceeding the maximum pressure the NerveGuard limits the injection pressure. The user can slightly release force and proceed injection beyond the limitation value.

The NerveGuard pressure monitor is a disposable manometer for objective monitoring of injection pressure during administration of peripheral nerve blocks (PNB). Monitoring opening injection pressure with the NerveGuard helps identify potentially unsafe injections before they start. When the NervGuard measures high opening injection pressure and limits this pressure down to a maximum of 18Psi, the needle can be repositioned and the injection resumed.

Usually the operator creates a force on the plunger (F_O) on the filled syringe which leads to normal flow of anesthetic through a valve in the NerveGuard. At this time, the resistance force of the locking mechanism F_S is higher when F_O. The locking mechanism closes the valve as soon as the force F_O overshoots F_S. The flow is stopped immediately. The NerveGuard will prevent a flow of anesthetic and fullfill it's protective function. Upon release of pressure F_O the valve re-opens and the procedure can move on.

Determination methods and results of Substantial Equivalence Determination:

Intended Use	Result: Substantially Equivalent
Comparison of outer appearance and assemblies	Result: Substantially Equivalent
Accuracy test	Result: Substantially Equivalent
Stability of needle/ manometer connector	Result: Substantially Equivalent

Equivalence in materials used and design

Characteristics	**Predicate device** **K031128** **B-Smart** **MACOSTA MEDICAL**	**Subject Device** **NerveGuard** **Pajunk® GmbH Medizintechnologie**	***Result of comparison, if necessary with rationale***
Biocompatibility	Both devices are external communicating. Therefore and based upon ISO10993-1 biocompatibility applies.		Substantially equivalent
Packaging	Individually packed and sterilized or as set component. Single sterile in medical paper bag (heat sealed)	Individually packed and sterilized or as set component. Single sterile in Tyvek bag (heat sealed) As a set component packed in a rigid tray, wrapped and packaged in a soft blister pack (heat sealed).	Same packaging The PAJUNK® individual packaging was selected according to a validated sterilization and transportation process
Intended Use	The Macosta Medical B-Smart Nerve Block Injection Pressure Manometer is a disposable manometer for measuring injection pressure during administration of peripheral nerve blocks.	The NerveGuard Nerve Block Injection Pressure Limiter is a disposable manometer for measuring injection pressure during administration of peripheral nerve blocks.	Substantially equivalent
Overall design:	Materials: plastics No direct patient contact	Materials: Polycarbonate, HDPE No direct patient contact	Both devices do not have direct patient contact and are made from plastic materials
Picture			Both systems allow easy handling and connecting
connectivity	Distal connector:male Proximal connector: female	Distal connector: male Proximal connector: female	Both systems do have identical connectivity towards syringe and needle
Capacity	Indicates pressure with a cylindrical hub	Indicates pressure and limits pressure to <18psi (15psi tolerance +3)	Both systems are equivalent in scale
increments	Indicates: <15psi white 15psi – 20psi yellow >20psi red	Limits injection to <18psi (15psi tolerance +3)	Both systems are equivalent in scale

Characteristics	**Predicate device** **K031128** **B-Smart** **MACOSTA MEDICAL**	**Subject Device** **NerveGuard** **Pajunk® GmbH Medizintechnologie**	***Result of comparison, if necessary with rationale***
Mechanism	Membrane pushing coloured indicator plunger	Sealing/ blocking mechanism	Predicate roughly indicates pressure while subject device limits pressure Subject device protects patient against high pressure while predicate device just gives an indication. Subject device is substantially equivalent to the predicate.
Connectivity	ISO 594-1 and ISO 594-2 (Luer connectivity)	80369-7 (Luer connectivity) ISO 80369-6, -20 NRFit (connectors for neuroaxial applications)	standardized connectivities

Each of the materials used either in the Predicate Devices or the Subject Device are established materials used for manufacturing medical devices.

Equivalence in the Indications for use

Subject Device:

The NerveGuard Nerve Block Injection Pressure Limiter is a disposable manometer for measuring injection pressure during administration of peripheral nerve blocks.

Predicate Devices:

The Macosta Medical B-Smart Nerve Block Injection Pressure Manometer is a disposable manometer for measuring injection pressure during administration of peripheral nerve blocks.

Discussion

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

Conclusion: Substantially Equivalent

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.

The limits listed below are met by each device:

Limits for Residuals: 25ppm = 25µg/(g/device) of Ehyleneoxide (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

Sterilization of devices purchased bulk by Repackagers/ Relabellers/ Kit Manufacturers:

The NerveGuard 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 NerveGuard purchased bulk non-sterile.

Shelf Life

Efficacy of sterile product´s lifecycle has been validated.

Sterility tests have been performed using worst case devices already cleared for market and being packed in identical packaging (material and dimensions).

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 NerveGuard is an external communicating device with no direct patient contact. Therefore based upon ISO10993-1 biocompatibility is evaluated. Since biocompatibility of the materials used is proven with another device of the sponsor additional testing is obsolete and has not been carried out. Therefore and based upon sterilization validation and residuals validation the devices are considered to be biocompatible.

Technology Characteristics/ Performance Testing

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 connector 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
Accuracy of measuring	Internal protocol	n.a.	Pass
Compatibility LUER	Internal Protocol	n.a.	Pass
Compatibility NRFit	Internal Protocol	n.a.	Pass

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 demonstrates that the subject device is substantially equivalent to the predicate device.