



July 25, 2017

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

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

Re: K170305

Trade/Device Name: Spinal Manometer NRFit; Spinal Manometer LUER  
Regulation Number: 21 CFR 880.2500  
Regulation Name: Spinal Fluid Manometer  
Regulatory Class: Class II  
Product Code: FMJ  
Dated: June 9, 2017  
Received: June 15, 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, MTP, 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

## Indications for Use

510(k) Number (if known)

K170305

Device Name

Spinal Manometer NRFit

Spinal Manometer LUER

Indications for Use (Describe)

The Spinal Manometer NRFit/ Spinal Manometer LUER is intended to measure the pressure of the Cerebrospinal Fluid (CSF) during a lumbar puncture procedure.

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: 2017-07-20****Document Control Number: *K170305*****510(k) owner:**

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Establishment Registration Number: **9611612****Submitter Information/ production site:**

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**Device Information:**

Device Name:	<b>Spinal Manometer NRFit</b> <b>Spinal Manometer LUER</b>
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 straÙe 45 65203 Wiesbaden Germany, Hessen <b>Establishment Registration Number:</b> 3002807090
Document Control Number	<i>K170305</i>
Classification Name:	manometer, spinal-fluid
Classification Reference:	21 CFR 880.2500
Product Code:	FMJ
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	General Hospital
Predicate Device by competitor	K032432 BUSSE HOSPITAL DISPOSABLES SPINAL MANOMETER

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

The manometer is considered a Class II medical device as defined in 21 CFR §880.2500, product code FMJ.

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.

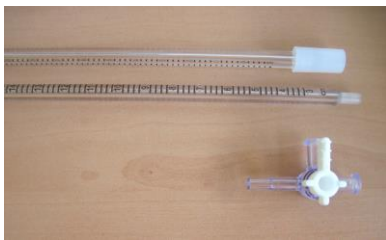

**Indications for use**



The Spinal Manometer NRFit/ Spinal Manometer LUER is intended to measure the pressure of the Cerebrospinal Fluid (CSF) during a lumbar puncture procedure.

**Determination methods and results of Substantial Equivalence Determination:**

Intended Use	Result: Substantially Equivalent
Comparison of outer appearance and assemblies	Result: Substantially Equivalent
Leak Tightness test	Result: Substantially Equivalent
Stability of connections, mechanical test	Result: Substantially Equivalent
Stability of needle/ manometer bridge	Result: Substantially Equivalent

**Equivalence in materials used**

<b>Characteristics</b>	<b>Predicate device 1</b> Spinal manometer <b>K032432 Busse Hospital Disposables</b>	<b>Subject Device</b> Spinal manometer <b>Pajunk® GmbH Medizintechnologie</b>	<b>Result of comparison, if necessary with rationale</b>
Biocompatibility	The spinal manometer does neither have direct nor indirect patient contact. Therefore and based upon ISO10993-1 biocompatibility testing is obsolete.		Substantially equivalent
Packaging	The Spinal Manometer is placed in a rigid tray composed of high impact plastic (polystyrene). The tray is wrapped and packaged in a soft pouch with Tyvek lid. The pouch is 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 set packaging The PAJUNK® individual packaging was selected according to a validated sterilization and transportation process
Overall design: spinal Manometer	Materials: Polyethylene, Polycarbonate No patient contact	Materials: PVC, Polycarbonate, HDPE No patient contact	Both spinal manometers do not have direct patient contact and are made from plastic materials
Scale (manometer)	 0,2 cm scale	 1 cm scale	Both systems allow easy reading of spinal pressure in cmHg increments

<b>Characteristics</b>	<b>Predicate device 1</b> Spinal manometer <b>K032432 Busse Hospital Disposables</b>	<b>Subject Device</b> Spinal manometer <b>Pajunk® GmbH Medizintechnologie</b>	<b>Result of comparison, if necessary with rationale</b>
Three-way-stopcock	 <p>Detachable/ slip on three –way-stopcock LUER Distal connector: male Proximal connector: female</p>	 <p>Three-way-stopcock, not detachable (glued), LUER or NRFit Distal connector: male Proximal connector: female</p>	Both systems use 3-way stopcocks
Capacity	Length: 36cm, extension up to 55cm possible	Length: 34cm, extension for 20cm (54cm in total) or rather 40cm (74cm in total) possible	Both systems can be extended
Connectivity	ISO 594-1 and ISO 594-2 (Luer connectivity)	80369-7 (Luer connectivity) ISO 80369-6, -20 NRFit (connectors for neuroaxial applications)	All 3-way stopcock have 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 Spinal Manometer NRFit/ Spinal Manometer LUER is intended to measure the pressure of the Cerebrospinal Fluid (CSF) during a lumbar puncture procedure.

**Predicate Devices:**

The device is intended to measure the pressure of the Cerebrospinal Fluid (CSF) during lumbar puncture procedure.

**Discussion**

The indications for use as well as the intended use of the predicate device and of the subject device are substantially 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 <sup>-6</sup>
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<sup>-6</sup> 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 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

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

The spinal manometers 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 spinal manometers 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 and markings) 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 spinal manometer does neither have direct nor indirect patient contact. Therefore and based upon ISO10993-1 further biocompatibility testing is obsolete.

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 Markings	Internal protocol	n.a.	Pass
Durability of Markings	Internal Protocol	n.a.	Pass
Stability of Glue Connection	Internal Protocol	n.a.	Pass
Compatibility LUER	Internal Protocol	n.a.	Pass
Compatibility NRFit	Internal Protocol	n.a.	Pass
Batch Inspection report	Internal Protocol	n.a.	Pass

**Conclusion:**

The predicate devices chosen for demonstrating substantial equivalence is the BUSSE HOSPITAL DISPOSABLES SPINAL MANOMETER manufactured by BUSSE HOSPITAL DISPOSABLES, INC. p.o. box 2156 huntington, CT 06484 and cleared by the Food and Drug Administration for market under K032432, product code FMJ, review panel General Hospital.

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 already cleared for market and therefore demonstrated to perform as accurate as the legal predicate device.