May 3, 2018

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

Re: K172777
Trade/Device Name: Catheter Clamping Adapter NRFit (ISO80369-6) and Catheter Clamping Adapter LUER (ISO80369-7)
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO
Dated: April 4, 2018
Received: April 6, 2018

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.

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.

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,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172777

Device Name
Catheter Clamping Adapter NRFit (ISO80369-6) and Catheter Clamping Adapter LUER (ISO80369-7)

Indications for Use *(Describe)*
The Catheter Clamping Adapter, a connection device, is used to provide various anesthetic and fluid administration devices with a single, common access point to a catheter for delivery of anesthetics.

The connector is used in conjunction with catheters for continuous administration of anesthetic agents.

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: 2018-04-25

Document Control Number: K172777

510(k) owner:

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Establishment Registration Number: **9611612**

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Device Name and Classification Details

Device Information:

Device Name:	**Catheter Clamping Adapter NRFit™ (ISO80369-6)** **Catheter Clamping Adapter 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	**K172777**
Trade Name:	**Clamping Adapter**
Common name	**Catheter Connector**
Classification Name**:**	**Anaesthesia Conduction Catheter**
Classification Reference**:**	**21 CFR 868.5120**
Product Code:	**BSO**
Regulatory Class:	**II**
Panel:	**Anesthesiology**

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

The device is intended to provide a specified connection (either NRFit™ Connector according to ISO80369-6 or LUER-Connector according to ISO80369-7) to an unspecified proximal end of a 20G anesthesia conduction catheter (epidural or peripheral). Therefore it may also be considered an accessory for epidural and peripheral anesthesia conduction catheters.

The Catheter Clamping Adapter is considered a Class II medical device according to the predicate device as defined in 21 CFR §868.5120, product code BSO.

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.

Indications for use

The Catheter Clamping Adapter, a connection device, is used to provide various anesthetic and fluid administration devices with a single, common access point to a catheter for delivery of anesthetics.

The connector is used in conjunction with catheters for continuous administration of anesthetic agents.

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** **K022019** **BBraun Perifix Catheter Connector**	**Subject Device** **Catheter Clamping Adapter**	***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	A connection device used to provide various anesthetic and fluid administration devices with a single, common access point to an 18 or 20 gauge Perifix catheter for delivery of anesthetics. The connector is used in conjunction with 18 or 20 gauge Perifix catheters for continuous administration of anesthetic agents.	The Catheter Clamping Adapter, a connection device, is used to provide various anesthetic and fluid administration devices with a single, common access point to a catheter for delivery of anesthetics. The connector is used in conjunction with catheters for continuous administration of anesthetic agents.	Substantially equivalent Size limitation in predicate device has been altered by K032144 and K033952 of predicate´s sponsor
Overall design:	Adapter clamps catheter	Adapter clamps catheter	Substantially equivalent

Characteristics	**Predicate device** **K022019** **BBraun Perifix Catheter Connector**	**Subject Device** **Catheter Clamping Adapter**	***Result of comparison, if necessary with rationale***
Picture			Both systems allow easy handling and connecting with one hand
Materials used	Plastics, rubber	Body Polycarbonate Clamping seal Silicone	Similar 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.
Tightness	Leak tight under normal conditions when used according to instructions for use	Leak tight under normal conditions when used according to instructions for use	identical
Tensile Force	≥ 8N	≥ 8N	identical

Equivalence in the Indications for use

Subject Device:

The Catheter Clamping Adapter, a connection device, is used to provide various anesthetic and fluid administration devices with a single, common access point to a catheter for delivery of anesthetics.

The connector is used in conjunction with catheters for continuous administration of anesthetic agents.

Predicate Devices:

A connection device used to provide various anesthetic and fluid administration devices with a single, common access point to an 18 or 20 gauge Perifix catheter for delivery of anesthetics. The connector is used in conjunction with 18 or 20 gauge Perifix catheters for continuous administration of anesthetic agents.

Discussion

The intended use of the predicate devices and of the subject device are identical. The indications for use differ slightly but the differences do not raise different questions of safety or effectiveness.

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

Technology Characteristics/ Performance Testing

Subject Device:

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

Leak Tightness: Complies with internal protocol

Security of connection, tensile strength: Complies with internal protocol

Predicate Devices:

Leak Tightness: Complies with internal protocol of the sponsor

Security of connection, tensile strength: Complies with internal protocol of the sponsor

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 of Ehyleneoxide and Ethylene chlorhydrine are met.

Limit for Pyroburden/ endotoxine is met.

The clamping adapters 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 catheter clamping adapters 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

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
Leak Tightness	Internal Protocol	n.a.	Pass
Security of connection	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 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.