DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 13, 2016

Pajunk Gmbh Medizintechnologie
Christian Quass
Director, Regulatory Affairs
Karl-Hall-Str. 1
78187 Geisingen
Baden-Wuerttemberg, Germany

Re: K152952
Trade/Device Name: Over-the-Needle (OTN) Catheter System E-Cath
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO, CAZ
Dated: June 10, 2016
Received: June 13, 2016

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 yours,

Michael J. Ryan -S

for Erin I. Keith, M.S.
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)*
K152952

Device Name
Over-the-Needle (OTN) Catheter System E-Cath

Indications for Use *(Describe)*
The Over-the-needle (OTN) Catheter System is indicated for delivery of medication for regional anesthesia and pain management. Route of administration may be intraoperative, percutaneous, or perineural. The Over-the-needle (OTN) Catheter System is contraindicated for the epidural space.

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: 2016-07-13

Document Control Number: K152952

510(k) owner:
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

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:	Over-the-needle (OTN) Catheter System “E-Cath”
Components:	SonoPlex cannula E-Cath catheter Locking cap Injection tube permanent cannula/ indwelling catheter Bacterial filter Optional FixoLong or FixoCath
Sterilization method:	Ethylene Oxide disposable device supplied sterile to the end user
Contract Sterilizer:	Sterigenics Germany GmbH Kasteler straße 45 65203 Wiesbaden Germany, Hessen **Establishment Registration Number:** 3002807090
Document Control Number	*K152952*
Classification Name:	Anesthesia Conduction Catheter
Classification Reference:	21 CFR §868.5120
Product Code:	BSO
Subsequent Product Code	CAZ
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology
Predicate Device:	K143164 Halyard – Irvine: On-Q QuikBloc Over-the-Needle (OTN) Catheter Set
Components of the device system already cleared by sponsor´s 510(k)s or exempt or class I:	SonoPlex cannula (K111374) E-Cath catheter (K033018, K013041) Locking cap (K082164) Injection tube (K082164) Permanent cannula (K033018, K082164) Bacterial filter (K082164) Optional FixoLong or FixoCath (K082164)

PAJUNK® GmbH Medizintechnologie is submitting this *510(k)* for Over-the-needle (OTN) Catheter System, brand name “E-Cath”.

It is considered a Class II medical device as defined in 21 CFR §868.5120, product code BSO.

The intended use as well as the individual components this system consist of have been cleared in several 510(k)s sent in earlier by the sponsor. However, the combinations of components as well as the brand names slightly vary from the subject device. Furthermore the intended use in cleared premarket notifications has been less specific than it is in this premarket submission according to 510(k). In order to make the clearance status of the subject device – E-Cath, formerly also called MultiSet Tsui – more obvious, sponsor decided to compile the data in one individual standalone 510(k) comparing the device to competitor´s predicate devices.

The technique – over the needle – is rarely identified in submissions with identical indications for use. Usually it is not mentioned whether the technique of placing a catheter is “over the needle” or “through the needle”. This detail in application method does not make any difference in evaluating safety, effectiveness and efficacy of the device itself from the technological point of view.

So substantial equivalence is based on earlier submissions by the sponsor as well as based on bench tests comparing the subject device with competitor´s devices.

The Over-the-needle (OTN) Catheter System is intended for use with adult patients.

Indications for use subject device:

The Over-the-needle (OTN) Catheter System is indicated for delivery of medication for regional anesthesia and pain management. Route of administration may be intraoperative, percutaneous, or perineural. The Over-the-needle (OTN) Catheter System is contraindicated for the epidural space.

Device Description:

The Over-the-needle (OTN) Catheter Systems are available in different designs with cannula and catheter in different sizes. The system includes: SonoPlex cannula, permanent cannula, E-Cath catheter, filter, FixoLong or FixoCath, locking cap and optional ultrasound cover.

Predicate Devices:

The predicate device for the Over-the-needle (OTN) Catheter System is:

- K143164 of Halyard – Irvine: On-Q QuikBloc Over-the-Needle (OTN) Catheter Set

Determination methods and results of Substantial Equivalence Determination:

Intended Use

Intended Use Subject Device

The Over-the-needle (OTN) Catheter System is indicated for delivery of medication for regional anesthesia and pain management. Route of administration may be intraoperative, percutaneous, or perineural. The Over-the-needle (OTN) Catheter System is contraindicated for the epidural space.

Intended Use K143164 (Predicate Device)

The ON-Q* QuikBloc* Over-the Needle Catheter Set is indicated for delivery of medication for regional anesthesia and pain management. Route of administration may be intraoperative, percutaneous, or perineural. The ON-Q* QuikBloc* Over-the-Needle Catheter Set is contraindicated for the epidural space.

Conclusion: Substantially Equivalent

Furthermore the comparing benchmarking tests described below have been conducted in order to verify substantial equivalence.

Needle: stability test bending rigidity

Reason for test: The needle has to demonstrate bending stability and resistance against breakage in order to resist forces reasonably assumed to be applied to the needle in situ under the defined intended use

Procedure of test: The test procedure is defined by international standard EN ISO 9626: Stainless steel needle tubing for manufacture of medical devices.

Pass/ Fail criteria: According to the standard the acceptance criterion of bending rigidity for the cannula is ≤0,48mm under an applied force of 15N by a span width of 17,5mm.

Results: The bending rigidity of the predicate device´s needles and the subject device´s needles is less than 0,46mm.

Conclusion: Substantially Equivalent

Needle: stability test bonding to hub

Reason for test: The needle has to demonstrate stability at the bonding of the hub in order to resist forces reasonably assumed to be applied to the needle in situ under the defined intended use.

Procedure of test: The test procedure is defined by international standard EN ISO 7864: Sterile hypodermic needles for single use

Pass/ Fail criteria: The acceptance criterion for the bond between hub and needle tube (pull-off force) is ≥44N.

Results: For the needles of the subject device and the needles of the predicate device a force significantly higher than the target value has to be applied. Therefore the predicate device´s needles as well as the subject device´s needles are substantially equivalent.

Conclusion: Substantially Equivalent

Needle: Penetration force

Reason for test: The needles have to demonstrate less trauma when applied with the patient under the intended use.

Procedure of test: According to international European standard EN 13097.

Pass/ Fail criteria: -none- objective comparison only.

Results: The subject device´s needles as well as the predicate device´s needles show equivalent penetration/ insertion forces.

Conclusion: Substantially Equivalent

Catheter: Leak Tightness

Reason for test: The catheter and its connections have to demonstrate stability and tightness in order to resist forces reasonably assumed to be applied to the catheter in situ under the defined intended use

Procedure of test: The test procedure is defined by international European standard DIN EN 1618.

Pass/ Fail criteria: The pass-fail-criteria are not defined by the standard and are defined through internal protocols based on risk assessment and clinical evaluation.

Results: The catheters of the subject device as well as the catheter of the predicate device meet the acceptance criterion.

Conclusion: Substantially Equivalent

Catheter: tensile strength

Reason for test: The catheter has to demonstrate stability and tensile strength in order to resist forces reasonably assumed to be applied to the catheter in situ under the defined intended use.

Procedure of test: The test procedure is defined by international European standard DIN EN 10555-1.

Pass/ Fail criteria: The pass-fail-criteria are not defined by the standard and are defined through internal protocols based on risk assessment and clinical evaluation.

Results: The catheters of the subject device as well as the catheter of the predicate device meet the acceptance criterion.

Conclusion: Substantially Equivalent

Catheter: Flow Rate

Reason for test: The catheter has to demonstrate a stable flow rate in order to perform properly in situ under the defined intended use.

Procedure of test: The test procedure is defined by international European standard DIN EN 10555-1.

Pass/ Fail criteria: The pass-fail-criteria are not defined by the standard and are defined through internal protocols based on risk assessment and clinical evaluation.

Results: The catheters of the subject device as well as the catheter of the predicate device meet the acceptance and have proven to have equivalent flow rates.

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 and are safe and effective.

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

Shelf Life

Efficacy of sterile product´s lifecycle has been validated using similar products and worst case devices.

Sterility tests have been performed using worst case devices with similar characteristics made from identical material after 5 years. The devices were found to be sterile after 5 years, the sterile barrier system is efficient.

Performance of the essential performance of the device (LUER connection, stability of bonding connections, catheter´s tensile strength, needle´s bending rigidity) has been tested with real time aged needles and catheters made from identical material employing identical processes and those are found to work properly. 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 components the system is assembled from have proven biocompatibility in former 510(k) files also containing the individual components.

The tests listed below have been conducted and accomplished successfully by components and worst case devices:

- *In vitro* Cytotoxicity_ISO 10993-5
- Irritation_ISO 10993-10
- *In vitro* Haemolysis Test on static conditions_ISO 10993-04
- Acute Systemic Toxicity_ISO 10993-11
- Test for delayed type hypersensitivity:ISO10993-10
- Reverse Mutation Assay_ISO 10993-03
- Implantation_ISO 10993-06
- Implantation Histopatology_ISO 10993-06

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

Technology Characteristics:

Besides bench testing recognized standards are applied as applicable for the subject device. Compliance is claimed for the standards listed below:

EN ISO 9626: Stainless steel needle tubing for manufacture of medical devices.

The cannula tubing of the cannula included in the subject device fulfills the requirements according to EN ISO 9626. Technological characteristics like material, surface finish, cleanliness, limits for acidity and alkalinity and size designation are complied with.

Regarding the requirement of bending rigidity and breaking resistance the cannula tubes are tested according to the standard (Annex C and D).

According to the standard the acceptance criterion of the bending rigidity for the cannula is ≤ 0,48mm. The applied force was 15N by a span width of 17,5mm. The bending rigidity of the tested cannulas is less than 0,46mm. Therefore the cannula meets this acceptance criterion.

The acceptance criterion of the breaking resistance is: not to break.

During the test the cannula is bended an angle, which is defined in the standard based on to the cannula size, for 20 periods. Means the cannula is bended in two directions. The tested cannulas did not break during the test. Therefore the cannula meets this acceptance criterion.

The cannulas fulfill all the requirements of EN ISO 9626.

EN ISO 7864: Sterile hypodermic needles for single use

The cannulas used comply with the requirements according to EN ISO 7864. Technology characteristics like Cleanliness, Limits for acidity or alkalinity, Limits for extractable metals, size designation, needle hub, sheath, tolerances, patency of lumen, freedom from defects, lubricant, needle point, packaging and labeling are in compliance.

Regarding the requirement of bond between hub and needle tube the cannula is tested according to the standard.

The acceptance criterion for the bond between hub and needle tube (pull-off force) is ≥44N.

Therefore the cannula meets the acceptance criterion.

The cannulas fulfill all the requirements of EN ISO 7864.

EN 13097: Hypodermic needles

The penetration force of the cannula is tested according to the standard (Annex D). The standard does not include acceptance criteria but is meant to provide an objective test method.

Compared to the predicate device PAJUNK´s cannula is substantially equivalent.

DIN EN 10555-1: Intravascular catheters – sterile and single use catheters – Part 1: General requirements

The catheter fulfills the requirements of the standard DIN EN 10555-1. Technology characteristics like X-ray visibility, biocompatibility, surface, hub, lateral openings, catheter tip, size designation, packaging and labelling are met.

Tensile force, tightness and flow rate are tested according to the standard.

The standard does not give an acceptance criterion for the tensile force.

Due to this, PAJUNK® set the acceptance criterion for this to an internally defined acceptable value to be met without tear off. The catheters of the E-Cath System meet the acceptance criterion.

For the test on leak tightness, the catheter system has to be tight for a defined period of time as well as a defined pressure. Both systems are tight during the test.
Also for the flow rate no acceptance criterion is given The specification of PAJUNK® catheters regarding the flow rate is internally defined by the sponsor based on risk management and clinical evaluation. The flow rate of the tested E-Cath catheter meets the acceptance criterion.
The requirement of corrosion resistance does not apply due to no metal components of the catheter.
The requirement of high-performance injection does not apply because the catheter is not intended for high-performance injection.
The catheters fulfill all the requirements.

DIN EN 1618: Catheters other than intravascular catheters – Test methods for common properties

The catheter of the E-Cath System fulfills the requirements of the standard DIN EN 1618. Requirements like tensile properties, tightness, flow rate as well as the safety of connectors are tested according to the standard.
The standard does not give an acceptance criterion for the tensile force.
Due to this, PAJUNK® set the acceptance criterion for this to an internally defined must-value without tear off.
The catheters of the E-Cath System meet the acceptance criterion.
For the test on tightness, the catheter system has to be tight for a defined period of time as well as a defined pressure. Both systems are tight during the test.
Also for the flow rate no acceptance criterion is given.
The specification of PAJUNK® catheters regarding the flow rate is defined as internal must-value. The flow rate of the tested E-Cath catheter meets the acceptance criterion.
The requirement of corrosion resistance does not apply due to no metal components of the catheter

The catheters and needles fulfill all the requirements for the essential technological characteristics.

As proven in the predicate device discussion´s bench testing as well as in the bench testing and standard compliance testing of the subject device the Over-the-needle (OTN) Catheter System E-Cath and its predicate device have the same basic fundamental technological characteristics.

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, bench testing and bench marking demonstrates that the subject devices are substantially equivalent to the predicate devices and substantially equivalent in technical description to devices already cleared for market and therefore demonstrated to be as safe and effective as the legal predicate devices.