December 29, 2020

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

Re: K202699
Trade/Device Name: E-Cath STIM acc. Tsui
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: Class II
Product Code: CAZ, BSP, BSO
Dated: December 4, 2020
Received: December 14, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant 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)*
K202699

Device Name

E-Cath STIM acc. Tsui

Indications for Use *(Describe)*

The E-Cath STIM acc. Tsui System is indicated for delivery of medication for regional anesthesia and pain management. Route of administration may be intraoperative, percutaneous, or perineural. To assist the physician pinpoint the area of application an electrical stimulus can be applied to the conduction needle. After needle removal, to assist the physician pinpoint conduction catheter placement, an electrical stimulus can be applied to the conduction catheter tip via the catheter adapter.

The E-Cath STIM acc. Tsui 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.

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Special 510(k): Device Modification Premarket Notification Submission

PAJUNK®

Special 510(k) Summary as required by 21 CFR 807.92(c).

Date of Preparation: 2020-12-27

Document Control Number: K202699

Special 510(k) owner:

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Special 510(k): Device Modification Premarket Notification Submission

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Device Information:

Device Name:	E-Cath STIM acc. Tsui
Components:	SonoPlex cannula E-Cath StimuLong catheter Locking cap Injection tube permanent cannula Bacterial filter
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	*K202699*
Device Name:	*E-Cath STIM* acc. Tsui
Classification Name:	*Anesthesia Conduction Kit*
Classification Reference:	*21 CFR 868.5140*
Product Code:	*CAZ*
Subsequent Classification Name #1:	*Anesthesia Conduction Needle*
Subsequent Classification Reference #1:	*21 CFR 868.5150*
Subsequent Product Code #1:	*BSP*
Subsequent Classification Name #2:	*Anesthesia Conduction Catheter*
Subsequent Classification Reference #2:	*21 CFR 868.5120*
Subsequent Product Code #2:	*BSO*
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology
Predicate Device:	K152952 E-Cath
Second Predicate Device:	K033018 StimuLong

Components of the device system already cleared by sponsor´s 510(k)s or exempt or class I:	SonoPlex cannula (K111374) StimuLong catheter (K033018, K013041, K062900) Locking cap (K082164 et al.) Injection tube (K082164 et altera) Permanent cannula (K033018, K082164 et al.)

PAJUNK® GmbH Medizintechnologie is submitting this *Special 510(k) for a modification* of the Over-the-needle (OTN) Catheter System, brand name “E-Cath”, intended to be brand-named E-Cath STIM acc. Tsui.

It is considered a Class II medical device as defined in 21 CFR §868.5140 anesthesia conduction kit, product code CAZ (Subsequent Codes: 21 CFR §868.5120 catheter, conduction, anesthetic, product code BSO and 21 CFR §868.5150 Anesthesia conduction needle, product code BSP.

The intended use as well as the individual components this system consist of have been cleared in different 510(k)s sent in earlier by the sponsor and shall be combined under a new device name. So the E-Cath K152952 shall be equipped with a stimulation catheter (in K152952 the catheter described is a non-stimulation catheter but the stimulation catheter in K152952 is already optionally listed) as it is described in the 510(k)s for the second predicate device StimuLong K033018.

The intended use of the E-Cath STIM acc. Tsui shall be extended to one more specific use as defined in an earlier 510(k) which serves as reference device.

In order to make the clearance status of the subject device – E-Cath STIM acc. Tsui – more obvious, sponsor decided to compile the data in one individual standalone Special 510(k) describing the modifications more clearly.

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 of the modifications is based on earlier submissions by the sponsor and verified through Design verification process.

Indications for use subject device:

The E-Cath STIM acc. Tsui System is indicated for delivery of medication for regional anesthesia and pain management. Route of administration may be intraoperative, percutaneous, or perineural. To assist the physician pinpoint the area of application an electrical stimulus can be applied to the conduction needle. After needle removal, to assist the physician pinpoint conduction catheter placement, an electrical stimulus can be applied to the conduction catheter tip via the catheter adapter.

The E-Cath STIM acc. Tsui 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, locking cap.

Predicate Device:

The predicate device for the E-Cath STIM is K152952 E-Cath manufactured by PAJUNK® GmbH Medizintechnologie.

Second Predicate Device:

The second predicate device for the E-Cath STIM is StimuLong K033018 manufactured by PAJUNK® GmbH Medizintechnologie.

Determination methods and results of Substantial Equivalence Determination:

Intended Use

Intended Use Subject Device

The E-Cath STIM acc. Tsui System is indicated for delivery of medication for regional anesthesia and pain management. Route of administration may be intraoperative, percutaneous, or perineural. To assist the physician pinpoint the area of application an electrical stimulus can be applied to the conduction needle. After needle removal, to assist the physician pinpoint conduction catheter placement, an electrical stimulus can be applied to the conduction catheter tip via the catheter adapter.

The E-Cath STIM acc. Tsui System is contraindicated for the epidural space.

Intended Use K152952 E-Cath (Predicate 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 K033018 StimuLong (Second Predicate Device)

The Pajunk Stimulong Plus Catheter Sets are intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. Continuous delivery is accomplished using the conduction catheter. To assist the physician pinpoint the area of application an electrical stimulus can be applied to the conduction needle and after placement of the conduction catheter to its tip via the catheter adapter.

Discussion

The wording has been updated, but the general intended use remains the same. In addition K033018 has a technical amendment for electrical position control which is state of the art and which shall be added to the subject device´s intended use. This amendment which is the reason for this modification of the device and the 510(k) is both, state of the art as well as cleared by FDA in earlier 510(k)s.

Conclusion: neutral modification

Special 510(k): Device Modification
Premarket Notification Submission

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Side-by-side comparison table

Characteristics	Subject Device E-Cath STIM acc. Tsui Pajunk® GmbH Medizintechnologie	Predicate Device K152962 E-Cath E-Cath Over-the-needle (OTN) Catheter System Pajunk® GmbH Medizintechnologie	Predicate Device K033018 StimuLong Pajunk® GmbH Medizintechnologie	*Result of comparison, if necessary with rationale*
Biocompatibility	ISO 10993-1 compliant material & set components			Identical
Labeling	21 CFR and European Medical Devices Directive compliant			identical
Packaging	Packed in a hard blister package consisting out of GGG PET foil and Tyvek (heat sealed) or in a foil bag with tyvek.	Packed in a hard blister package consisting out of GGG PET foil and Tyvek (heat sealed) or in a foil bag with tyvek.	Packed in a hard blister package consisting out of GGG PET foil and Tyvek (heat sealed) or in a foil bag with tyvek.	identical
Overall design: Set components	Needle: SonoPlex with stimulation and permanent cannula Stimulation Catheter Injection tube Retaining clip Filter FixoLong or FixoCath	Needle: SonoPlex with stimulation and permanent cannula Catheter Injection tube Retaining clip Filter FixoLong or FixoCath	Needle: SonoPlex with stimulation and permanent cannula Stimulation Catheter Injection tube Retaining clip Filter FixoLong or FixoCath	Difference: Stimulation catheter cleared for the intended use in K033018 instead of non-stimulation catheter
Technology	Catheter-over needle	Catheter-over-needle	Catheter through needle	Technologically equivalent technique, both state of the art
technical specifications	Stainless steel needle and Polyamide catheter	Stainless steel needle and Polyamide catheter	Stainless steel needle and Polyamide catheter	identical
principles of operation	Penetrate skin using needle, position control Dual Guidance, Placement of catheter, position control Dual Guidance, injection of anesthetic agent	Penetrate skin using needle, position control Dual Guidance, Placement of catheter, position control ultrasound, injection of anesthetic agent	Penetrate skin using needle, position control Dual Guidance, Placement of catheter, position control Dual Guidance, injection of anesthetic agent	Enhancement of technique by adding stimulation for dual guidance

Special 510(k): Device Modification
Premarket Notification Submission

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Characteristics	Subject Device E-Cath STIM acc. Tsui Pajunk® GmbH Medizintechnologie	Predicate Device K152962 E-Cath E-Cath Over-the-needle (OTN) Catheter System Pajunk® GmbH Medizintechnologie	Predicate Device K033018 StimuLong Pajunk® GmbH Medizintechnologie	*Result of comparison, if necessary with rationale*
Materials	Stainless steel and plastics	Stainless steel and plastics	Stainless steel and plastics	identical
Feature: Echogenicity	Cannula & Catheter	Cannula & Catheter	none	Identical, technological enhancement in subject device compared to second predicate device
Feature: Stimulation	Cannula and catheter	Cannula	Cannula and catheter	equivalent
Feature: Connectivity	ISO80369-6 (NRFit®)and 80369-7 (LUER) Connectivity		LUER Connectivity	Identical, made fit with state of the art

The specifications for the stimulation catheters – material, indications for use, diameter 20G – are absolutely the same.

NAME OF COMPONENT		MATERIAL	BODY CONTACT
E-Cath STIM catheter	Tubing	PA	Direct, limited
	Stimulating knob	2.0771 gold plated	Direct, limited
	Wire	1.4310 stainless steel	Indirect, limited
	Glue	Loctite	No contact at all

	StimuLong K033018	E-Cath Stim K202699	Discussion
material	Polyamide, transparent	Polyamide, transparent	Identical
diameter	20G	20G	Identical

Special 510(k): Device Modification

Premarket Notification Submission

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	StimuLong K033018	E-Cath Stim K202699	Discussion
length	500mm, 600mm, 900mm	68mm 82mm 101mm 114mm	Made fit to kit, no effect on indications for use, safety or effectiveness (Negligible less dead space volume)
distal tip design	central orifice	central orifice	
proximal tip design	central orifice	central orifice (lateral opening where the indwelling cannula begins)	Equivalent; the lateral opening as cleared in K152952 does not have an effect on safety or effectiveness
radiopacity	radiopaque stripe (tungsten)	radiopaque stripe (tungsten)	Identical
echogenicity	standard	standard	Identical
marking	360° circumflex	360° circumflex	Identical
marking material	TPU 73 black	TPU 73 black	Identical
packaging	container	PE foil bag	Equivalent
stimulation	yes, via golden stimulating knob and stimulating stylet	yes, via golden stimulating knob and stimulating stylet	Identical
fixation	stimulating clamping adapter	stimulating cannula hub	Identical

Furthermore the benchmarking tests described below have been conducted for the subject device as they are conducted for the predicate device and its reference devices in order to verify compliance with international recognized standards.

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 subject/predicate/reference device´s needles (as they are the same) is less than 0,46mm.

Conclusion: Substantially Equivalent. In compliance

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 subject/predicate/reference device´s needles (as they are the same) a force significantly higher than the target value has to be applied.

Conclusion: Substantially Equivalent, in compliance

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/predicate/reference device´s needles (as they are the same) show appropriate penetration/ insertion forces.

Conclusion: Substantially Equivalent, in compliance

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 subject/predicate/reference device´s catheters (as they are the same) meet the acceptance criterion.

Conclusion: Substantially Equivalent, in compliance

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 subject/predicate/reference device´s catheters (as they are the same) meet the acceptance criterion.

Conclusion: Substantially Equivalent, in compliance

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 subject/predicate/reference device´s catheters (as they are the same) meet the acceptance criterion and have proven to supply appropriate flow rates.

Conclusion: Substantially Equivalent, in compliance

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 the predicate device and the reference device as well as 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, 5th 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 needles are in compliance.

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 Systems 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. All systems are tight during the test.

Also for the flow rate no acceptance criterion is given 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 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. All 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 catheters and needles fulfill all the requirements for the essential technological characteristics.

As proven in earlier Submissions of the predicate device as well as of the reference devices basic fundamental technological characteristics as described above are met.

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 bench testing demonstrates that the subject devices are the same as the predicate device and the reference devices and identical in technical description to those devices already cleared for market and therefore demonstrated to be as safe and effective as the legal predicate devices.

Based on the clinical evaluation, the biocompatibility testing and the bench testing conducted, safe performance of the E-Cath STIM is demonstrated.