MAR - 1 2012

Premarket Notification Submission 510(k)

K113188

PAJUNK MEDIZINTECHNOLOGIE

Summary of Safety and Effectiveness

Date of Preparation: October 27th 2011

Submitter Information/ production site:

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Establishment Registration Number: **9611612**

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Contract Sterilizer:

Ethylene Oxide;
External service provider, validated procedure.

Device Information:

Device Name:	**Sono-Series Kits (needles, catheters)**
Trade Names:	SonoLong, SonoLong Sono, SonoLong Curl Sono, StimuLong Sono, PlexoLong Sono, SonoLong NanoLine
Components:	Kits consisting of catheter, cannula/needle, filter, syringe, filter fixation device, adapter and common hospital supplies
Availability:	The components are available separately; non sterile, to be sterilized with EO for kit suppliers
Common Name:	SonoLong set, needles and catheters
Classification Name:	Anesthesia conduction kit
Classification Reference:	21 CFR §868.5140, April 1, 2011
1st Subsequent Classification Name	Anesthesia conduction needle
1st Subsequent Classification Reference	21 CFR §868.5150, April 1, 2011

2nd Subsequent Classification Name	Anesthesia conduction catheter
2nd Subsequent Classification Reference	21 CFR §868.5120, April 1, 2011
Product Code:	CAZ, BSP, BSO
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology
Predicate Devices:	1) K033018 PAJUNK® **StimuLong** Plus Catheter sets PAJUNK® GmbH Medizintechnologie, Geisingen 2) K013041 PAJUNK® **PlexoLong** Anaesthesia sets PAJUNK® GmbH Medizintechnologie, Geisingen 3) K111374 PAJUNK® **SonoPlex STIM** SONO-SERIES CORNERSTONE TECHNIQUE, PAJUNK® GmbH Medizintechnologie, Geisingen

Indications for use:

The PAJUNK® Sono-Series Kits SonoLong, SonoLong Sono, PlexoLong Sono, StimuLong Sono, SonoLong NanoLine and SonoLong Curl Sono are intended for delivery of continuous conduction anesthesia and/ or analgesia of peripheral nerves for up to 72 hours. Continuous delivery for up to 72 hours is accomplished using the Polyamide indwelling catheter. Optionally an electrical stimulus may be applied to assist the physician pinpoint the area of application.

Device Description:

The PAJUNK® Sono-Series Kits are single use sterile and non-pyrogenic kits basically consisting of catheters and cannulas as well as of optional components like Adapter, syringe, filter, filter fixation device and common hospital supply; used to gain entry or puncture the tissue and inject anesthetics to induce single shot and continuous regional anesthesia and analgesia for pain relief.

An electrical stimulus may be applied to the tip of the cannula/ needle (former PlexoLong series) and/or the tip of the catheter (former StimuLong series) via cable and connector to assist the physician pinpoint the area of application.

The Sono-Cannulas/ needles are standard cannulas/ needles (cleared by several PMN-submissions) equipped with the CornerStone technique in order to significantly enhance ultrasound visibility.

The Sono-catheters are standard anaesthesia conducting catheters equipped with an inner coil (cleared by several PMN-submissions) in order to enhance ultrasound visibility and device stability/ ergonomical features.

This submission of a 510(k) merely is due to new brand names than to introduce new techniques or technologies.

Predicate Devices:

The components the Sono-Series Kits consist of are already cleared in the predicate devices' 510(k) but now are assigned a new brand name.

Predicate devices with identical or at least partial identical indications of use are:

1) K033018 PAJUNK® StimuLong Plus Catheter sets, Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen
2) K013041 PAJUNK® PlexoLong Anaesthesia sets, Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen
3) K11374 PAJUNK® SonoPlex STIM SONO-SERIES CORNERSTONE TECHNIQUE, Manufacturer: PAJUNK® GmbH Medizintechnologie, Geisingen

The detailed discussion of substantial equivalence can be found in Section 12 of this submission.

Sterilization

The contract sterilizer and the sterilizing process are identical to the process and sterilizer used for all PAJUNK® - manufactured and purchased devices which are already cleared for market or exempt.

Neither Cornerstone-technique nor the coil inside the catheter do neither influence sterilization process nor shelf life properties.

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.

Efficacy of sterile product's lifecycle has been validated for a period of 10 years now. Shelflife is set to 5 years.

Biocompatibility:

All cannulas comply with ISO 10993-1, 2nd and 3rd edition.

Technology Characteristics:

The components are listed in a table in section 11 of this submission. Shelf life and impact of sterilization and storage on the devices has been proven and found to be safe and effective.

Each component shall be available separately, sterile and non-sterile, to be used with kit packaging in different configurations.

Conclusion:

The comparison between the predicate devices and the subject device in section 12 of this submission as well as the validated sterilization process and the results of the bench testing and bench marking demonstrates that the proposed devices are substantially equivalent (identical) to the predicate devices and identical in technical description to devices already cleared for market and therefore demonstrated to be safe and effective.

Based on the clinical evaluation, the biocompatibility testing and the bench testing conducted, safety and effectiveness as well as efficacy of the Cornerstone/ Sono-technique is demonstrated for each type of kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Christian G. Quass
Director Regulatory Affairs, Safety Official
Pajunk GmbH
Karl-Hall-Strasse 01
78187 Geisingen
GERMANY

MAR - 1 2012

Re: K113188
Trade/Device Name: Sono-Series Kits for Anaesthesia / Analgesia Conduction
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ, BSP, BSO
Dated: February 15, 2012
Received: February 21, 2012

Dear Mr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number:

Device Name: **Sono-Series Kits for anaesthesia/ analgesia conduction**

Brand name: **SonoLong, SonoLong Sono, PlexoLong Sono, SonoLong Curl Sono, StimuLong Sono, SonoLong NanoLine**

Indications for Use:

The PAJUNK® Sono-Series Kits SonoLong, SonoLong Sono, PlexoLong Sono, StimuLong Sono, SonoLong NanoLine and SonoLong Curl Sono are intended for delivery of continuous conduction anesthesia and/ or analgesia of peripheral nerves for up to 72 hours. Continuous delivery for up to 72 hours is accomplished using the Polyamide indwelling catheter. Optionally an electrical stimulus may be applied to assist the physician pinpoint the area of application.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K113188

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