FEB 29 2012

Summary of Safety and Effectiveness K113207

Date of Preparation: October 27th 2011

Submitter Information/ production site:
Pajunk GmbH
Karl-Hall-Strasse 01
78187 Geisingen
Germany
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
Establishment Registration Number: **9611612**

Contact:
Christian G. H. Quass
Director Regulatory Affairs, Safety Official
Patricia Weisbrod, *Regulatory Affairs*
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
E-Mail: christian.quass@pajunk.com
E-Mail: patricia.weisbrod@pajunk.com

USA Contact:
PAJUNK MEDICAL SYSTEMS
6611 Bay Circle, Suite 100
Norcross, GA 30071
Phone: (770) 493 - 6832 ext.111
Fax: (678) 514 - 3388
Cell: (770) 330 - 2724
richard.fischer@pajunk-usa.com

Contact
Richard Fischer MD
President
Fon: +01(0)770-493-6832 Ext 111
Fax: 678 5143388
E-Mail: Richard.fischer@pajunk-usa.com

Contract Sterilizer:
Ethylene Oxide;
External service provider, validated procedure.

Device Information:

Device Name:	cannulas/ needles enhanced for ultrasound visibility for anesthesia and analgesia
Trade Names:	Tuohy Sono, SonoTAP, Quincke Sono, Chiba Sono and Crawford Sono
Common Name:	Anaesthesia conduction needles/ cannulas
Classification Name	needle, conduction, anesthetic (w/wo introducer)
Classification Reference	21 CFR §868.5150, April 1, 2011
Product Code:	BSP
Establishment Registration Number:	9611612
Regulatory Class:	II
Panel:	Anesthesiology
Predicate Device:	**K040965 PAJUNK TUOHY NEEDLES, QUINCKE NEEDLES, CHIBA NEEDLES & CRAWFORD NEEDLES PAJUNK® GmbH Medizintechnologie, Geisingen**

Indications for use

The cannulas/ needles for anesthesia and analgesia enhanced for ultrasound visibility – Tuohy Sono, Sono TAP, Quincke Sono, Chiba Sono, Sono and Crawford Sono – are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of a catheter.

Device Description:

The cannulas/ needles for anesthesia and analgesia enhanced for ultrasound visibility are single use sterile and non-pyrogenic devices used to gain entry or puncture the tissue and inject anesthetics to induce single shot anesthesia and analgesia. The needles/ cannulas may be used during all anaesthetic and analgetic procedures according to the physicians indication.

Cannulas/ needles for anesthesia and analgesia enhanced for ultrasound visibility are standard cannulas/ needles equipped with CornerStone reflectors (cleared in K111374 – SonoPlex STIM) in order to significantly enhance ultrasound visibility.

The cannulas basically consist of stainless steel tubing and an epoxy glued polycarbonate hub. The tubing is optionally coated for better insertion properties with NanoLine, a copolymeric coating cleared for market in K053283.

In order to enhance ultrasound visibility the cannulas are equipped with a special reflector pattern named CornerStone imprinted to the cannulas surface. These reflectors are designed to optimally reflect ultrasound waves.

Brand names of the original file as well as the corresponding brand names of the subject file are:

Predicate: Tuohy	Subject: Tuohy SONO
Predicate: Quincke	Subject: Quincke SONO, SonoTAP
Predicate: Crawford	Subject: Crawford SONO
Predicate: Chiba (Facette)	Subject: Chiba SONO

Predicate Devices:

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

1) K040965 PAJUNK TUOHY NEEDLES, QUINCKE NEEDLES, CHIBA NEEDLES & CRAWFORD NEEDLES
   PAJUNK® GmbH Medizintechnologie, Gelsingen

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

Technological Characteristics:

Tip Specifications

The tips of the needles/ cannulas covered by this 510(k) are identical to the tips of the original predicate devices submission: Tuohy tip, Beveled tip (which is synonymously used with Chiba tip and facette tip), Crawford tip and Quincke tip (SonoTAP).

Length

The length of the needles/ cannulas subject to this 510(k) submission are identical to the lengths of the cannulas covered by the predicate device submission.

Tuohy: 20mm-180mm	Tuohy SONO : 20mm-180mm
Quincke: 20mm-180mm	Sono TAP, Quincke SONO : 20mm-180mm
Chiba: 20mm-180mm	Chiba SONO : 20mm-180mm
Crawford: 20mm-180mm	Crawford SONO : 20mm-180mm

Diameters

The diameters of the needles/ cannulas subject to this 510(k) submission are identical to the diameters of the cannulas covered by the predicate device submission.

Tuohy: 16G – 26G	Tuohy SONO : 16G – 26G
Quincke: 16G – 26G	Quincke SONO : 16G – 26G
Chiba: 16G – 26G	Sono TAP, Chiba SONO : 16G – 26G
Crawford: 16G – 26G	Crawford SONO : 16G – 26G

Technical specifications

The material of the cannulas/ needles tubing and hub of the predicate devices is identical to the material of the cannulas/ needles tubing and hub of the subject device. So are the glue connections. Both, subject device and predicate device are glued to the hub.

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. Cornerstone-technique does 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. Shelf life is set to 5 years.

Biocompatibility:

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

The stainless steel tubing of the Sono-needles/cannulas is identical to stainless steel tubing of the NanoLine-needles/cannulas as they were cleared for market in K040965, K000722 and K053283 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

The polycarbonate hub of the Sono-needles/cannulas is identical to the polycarbonate hub of the needles/cannulas as they were cleared for market in K040965, K000722 and K053283 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

The epoxy resin glue of the Sono-needles/cannulas is identical to the epoxy resin glue of the needles/cannulas as they were cleared for market in K040965, K000722 and K053283 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

The optional polymeric NanoLine coating of the Sono-needles/cannulas is identical to the polymeric NanoLine coating of the NanoLine-needles/cannulas as they were cleared for market in K053283 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

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.

Performance Testing

The needles/ cannulas have been subjected to standard testing applicable for all cannulas. Standard testing consists of bending stability and breaking resistance testing as well as of hub-to-needle-bondage testing. Due to technological equivalence the subject device is tested the same way as each cannula is tested at PAJUNK® GmbH Medizintechnologie. There are no special testing requirements defined, neither in incoming and in-process inspection routines nor in final testing.

Conclusion:

The comparison between the predicate devices – cannulas for anaesthesia conduction: Tuohy, Quincke, Crawford, Chiba – and the subject device – cannulas/ needles for anesthesia and analgesia enhanced for ultrasound visibility – 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 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 -technique is demonstrated for each type of cannula.

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.H. Quass
Director Regulatory Affairs
Pajunk GmbH
Karl-Hall-Strasse 1
Geisingen
GERMANY D-78187

FEB 2 9 2012

Re: K113207
Trade/Device Name: Cannulas/ Needles for Anesthesia and Analgesia Enhanced For Ultrasound Visibility
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
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,

for

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: Cannulas/ needles for anesthesia and analgesia enhanced for ultrasound visibility

Brand name: **Tuohy Sono, Sono TAP, Quincke Sono, Chiba Sono and Crawford Sono**

Indications for Use:

The cannulas/ needles for anesthesia and analgesia enhanced for ultrasound visibility – Tuohy Sono, Sono TAP, Quincke Sono, Chiba Sono and Crawford Sono – are intended for the transient delivery of anesthetics to provide regional anesthesia and analgesia or to facilitate placement of a catheter.

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)

L Schultz

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

510(k) Number: K113207