FEB - 6 2012

510(k) Summary

K113196

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**

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:

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

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:

External service provider located in Europe

Device Information:

Device Name:	**Vascular Sono vascular introducer cannula/needle**
Trade Names:	**Vascular Sono**
Common Name:	**Introducer**
Classification Name:	**Catheter introducer**
Classification Reference:	**21 CFR § 870.1340 April 1, 2011** PART 870 -- CARDIOVASCULAR DEVICES Subpart B--Cardiovascular Diagnostic Devices Sec. 870.1340 Catheter introducer (a) Identification. A catheter introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.
Establishment Registration Number:	**9611612**
Regulatory Class:	**II**
Product Code:	**DYB, OFC, OFD, OEX**
Panel:	**Cardiovascular**
Predicate Devices:	1. K020834 BD Introsyte Precision Introducer, BD Medical Systems 2. K030135 Safety Introducer Needle, BBraun Medical, Allentown

Indications for use

As provided in Sec. 870.1340 the PAJUNK®s Vascular Sono cannula/needle is an introducer used to facilitate placing an intravascular or intravenous device for diagnostical or interventional use through the skin into a vein or artery.

Device Description:

The Vascular Sono intravenous introducer cannula/needle is a single use sterile and non-pyrogenic medical device used to gain entry or puncture arteries and veins.

Predicate Devices:

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

1. K020834 BD Introsyte Precision Introducer, BD Medical Systems
2. K030135 Safety Introducer Needle, BBraun Medical, Allentown

Predicate Devices are marketed with additional equipment like safety mechanism and tear-away cannula. Basically, the introducer cannula of the predicate devices and the subject device is made from stainless steel.

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. The 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 proven 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 Vascular Sono is provided with enhanced ultrasound visibility. So is the predicate manufactured by BBraun. Additional Safety features like BBraun and BD offer are not part of the equipment. BD in Addition does provide a tear away cannula.
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-stability 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.

Summary of testing conducted on the Vascular SONO

Test Description	Result
Packaging: DIN EN 868-5:2009-09 Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods	-passed-
Packaging :"Bubble Emission test" acc. To ASTM E 515-05 4a	-passed-
Packaging :Rhodamin-B-Test, DYE-Test acc. To DIN 868-1 and ASTM F 1929-98	-passed-
Packaging: Peel-Test acc. To 868-10:2009-09 Annex C	-passed-
Microbiology/ Particles: LAL-Testing (Pyrogene)	-passed-
Microbiology/ Particles: Bioburden	-passed-
Microbiology/ Particles: Chemical Burden	-passed-
Microbiology/ Particles: Ethylene-Oxide Residuals acc. 10993-7	-passed-
Microbiology/ Particles: Test for sterility (per batch)	-passed-
Performance: Bending Rigidity/ Bending Stability	-passed-
Performance: Hub to needle bonding	-passed-
Performance: Breakage resistance	-passed-
Performance: Insertion force at point of entry	-passed-

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 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 proven 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

PAJUNK GmbH
C/O Mr. Christian G.H. Quass
Director Regulatory Affairs, Safety Official
Karl-Hall-Strasse 01
78187 Geisingen
Germany

FEB - 6 2012

Re: K113196/S001
Trade/Device Name: Vascular Sono vascular introducer cannula
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 9, 2012
Received: January 12, 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.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M.J. Hillebren

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for use

510(k) Number: K113196

Device Name: **Vascular Sono vascular introducer cannula**

Indications for Use:

As provided in Sec. 870.1340 the PAJUNK®s Vascular Sono cannula/needle is an introducer used to facilitate placing an intravascular or intravenous device for diagnostically or interventional use through the skin into a vein or artery.

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 Cardiovascular Devices

510(k) Number K113196