K 053283

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PAJUNK®
MEDIZINTECHNOLOGIE

510(k) Premarket Notification Submission: Summary of Safety and Effectiveness

Date of Preparation: October 27, 2005

Submitter Information/ production site:

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Device Information:

Trade Names: UniPlex NanoLine cannula,
PlexoLong-NanoLine set,
StimuLong-NanoLine set

Common Name: Anesthesia conduction kit/ cannula

Classification Name: Anesthesia conduction kit

Classification Reference: 21 CFR 868.5140, April 1. 2003

Poposed Classification: Regulatory Class: II

Proposed Product Code: CAZ

Predicate Devices:

1. **K000722:** Pajunk's Unipolar needles (UniPlex facet & Sprotte tip)
2. **K023218:** Pajunk's Unipolar needles (UniPlex Tuohy tip)
3. **K033018:** Pajunk's StimuLong set
4. **K013041, K023218** and **K042979:** Pajunk's PlexoLong set
5. **K994059:** HDC's Insul-Cote PTM needles and CLA kit (nerve stimulation), includes HDC's Neuro-Trace insulated needle.

Device Description:

Pajunk's **PlexoLong** and **StimuLong** sets consist of a Pajunk unipolar needle, an open ended conduction catheter and a catheter adapter, as well as a filter. The coating of the needle will be chnaged to **NanoLine.**

Pajunk's Unipolar needles marketed separately as single shot needles under the trade name **UniPlex** have a lacquer coating, which will be changed to **NanoLine** coating.

Only the coating material of the needles is affected by this change.

The anesthesia conduction catheters and the packaging materials are the same as those used for Pajunk's PlexoLong sets cleared for market by FDA under 510(k) numbers **K013041, K023218** and **K042979**.

The **NanoLine** coating is equivalent to HDC's Insul-Cote PTM needles and CLA kit (nerve stimulation) marketed under **K994059**. (In fact NanoLine is a better material because of a higher grade of purity. For a precise discussion of this topic see section 15 "Biocompatibility" of this submission of a special 510(k)).

The contract sterilizer other than a company name change (was IBA Griffith Micro Science, and now is Sterigenics) and the sterilizing process is the same as that used for Pajunk's PlexoLong sets.

Intended Use:

Pajunk's electrically insulated anesthesia conduction needles – **UniPlex-NanoLine cannula** – are intended for professional anesthetists to facilitate the localization of peripheral nerve bundles for transient delivery of anesthetics during regional anesthesia.

Pajunk's electrically insulated anesthesia conduction needles are also provided within **PlexoLong-** and **StimuLong-NanoLine sets** intended for professional anesthetists to facilitate the transient delivery of anesthetics during regional anesthesia.

The localization of the peripheral nerve bundle is facilitated via insulated needles and impulses from a neuro-stimulator. The electric current flows from the de-insulated needle tip. Muscles innervated by the stimulated nerve bundle will twitch as soon as the impulses reach a suitable setting.

Following nerve bundle localization, a catheter may be placed through the insulated anesthesia conduction needle close to the nerve for longer pain relief. After the needle has been withdrawn, the anesthesia conduction catheter allows for bolus injections or continuous infusion of local anesthetics into the peripheral nervous space.

Technology Characteristics:

Pajunk's anesthesia conduction needles & sets – **UniPlex-NanoLine cannula, PlexoLong- & StimuLong -NanoLine** sets – have the same technological characteristics as the predicate devices identified above.

Pajunk's anesthesia conduction needles & sets – **UniPlex-NanoLine cannula, PlexoLong-NanoLine set & StimuLong-NanoLine set** – are equivalent (in fact they are the same) in design, physical dimensions, luer hub, stilett, metal and plastics materials of needles and catheter, filter and connector, as well as packaging to **Pajunk's PlexoLong sets** cleared for

market by FDA under 510(k) numbers **K013041, K023218** and **K042979**. The NanoLine coating material is substantial equivalent to HDC's Insul-Cote PTM needles and CLA kit (nerve stimulation) marketed under **K994059.**

Biocompatibility testing of Pajunk's anesthesia conduction needles & sets – **UniPlex-NanoLine cannula, PlexoLong- & StimuLong -NanoLine sets** – has been accomplished with best results.

Summary of Design Control Activities

Changes that could affect performance of the cannula or result in a risk to the patient or the user were validated using the same protocols used to validate cleared devices. Results can be found in the summary of Risk-Analysis and in the Validation Reports of Section 09.

Conclusion:

The electrically insulating coating on the cannula is only a change in material for Pajunk GmbH products. The comparison between the predicate devices and the proposed devices demonstrates that the proposed devices are safe and effective when used according to the instructions for use supplied with the devices, as well as substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 2 2006

Mr. Christian Quaß
Manager Regulatory Affairs
Pajunk GmbH
Karl-Hall Strasse 1
78187 Geisingen
GERMANY

Re: K053283
Trade/Device Name: Pajunk Anesthesia Conduction NanoLine Coated Needles
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ, BSP
Dated: December 21, 2005
Received: December 27, 2005

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.

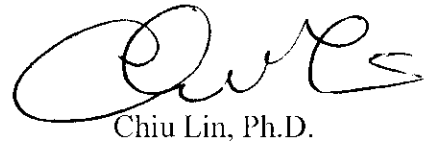
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 04

Indications for use

510(k) Number: **K053283**

Device Name: **Pajunk anesthesia conduction NanoLine coated needles**

Indications for Use:

The change of coating material from lacqueur to Parylene does not affect the Indications for use of the predicated devices marketed under

K042979 (Pajunk Plexolong Sets)

K033018 (Pajunk Stimulong Plus Catheter Sets)

K023218 (Pajunk Plexolong Sets)

K013041 (Pajunk Plexolong Anesthesia Sets)

K999722 (Unipolar Needles with Standard and Sprotte-tip)

The change in coating has no effect on the Indications for use of these devices already cleared for market.

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)

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