JUN 13 2006

K060311

510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

Date of Preparation: June 2006

Submitter Information/ production site:

Pajunk GmbH Medizintechnologie
Karl-Hall-Strasse 01
78187 Geisingen
Germany
Fon: +49(0)7704-9291-533
Fax: +49(0)7704-9291-605

Sterilizer:

SteriPro Lab & EO Facility
Dreieichstrasse. 7
64546 Mörfelden
Germany
Tel +49 6105 23091 or +49 (0) 6105 93470
Fax +49 6105 24760

Contact:

Christian Quass, Regulatory Affairs
Fon: +49(0)7704-9291-533
Fax: +49(0)7704-9291-605
E-Mail: christian.quass@pajunk.com

Establishment Registration Number:

9611612

Device Information:

Trade Names:	EpiLong, EpiLong Set, EpiLong II Safety Kit
Common Name:	Anesthesia Conduction Kit
Classification Name:	Anesthesia Conduction Kit
Classification Reference:	21 CFR § 868.5140, April 1, 2005,
Poposed Classification:	Regulatory Class II
Proposed Product Classification Code:	CAZ, Kit, Conduction Anesthesia
Panel:	Anesthesiology
Predicate Devices:	1. BBrauns Perifix **K813186** (also included in BBrauns Espocan **K932400**)

Device Description

Pajunk's **EpiLong** set is a single use, sterile, non-pyrogenic and latex free medical device kit. It is a epidural anesthesia kit consisting of a needle for insertion into the epidural space (a special Tuohy Cannula), a catheter for anesthesia administration to the epidural space, a flat filter as well as an adapter.

After administration of immediate epidural anesthesia, the epidural catheter may be placed via the cannula into the epidural space. The cannula is then withdrawn, leaving the Epidural Catheter tip in the epidural space for as long as determined by the professional anesthetist and the instructions for use (up to 72 hours).

Predicate Devices

The devices we claim substantial equivalence with is BBrauns Perifix **K813186** (also included in BBrauns Espocan **K932400**).

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

Sterilization

The contract sterilizer and the sterilizing process other than a company name change (was IBA Griffith Micro Science, and now is Sterigenics) is the same as that used for anesthesia conduction cannulae cleared for market by FDA under 510(k) number **K040965** and Kit Products Pajunks Stimulong Plus Plexus Catheter **K043130, K033018** Pajunks Plexolong Sets **K042979, K023218, K013041**.

Technology Characteristics:

The EpiLong kit provides a **Tuohy Cannula** with special tip through which the catheter is inserted directly in the epidural space for immediate administration of epidural anesthesia.

The **epidural catheter** is placed for prolonged (up to 72 hours) administration of epidural anesthesia. Safety is optimized by the use of the fixation adapter, Tuohy-Borst adapter and flat filter provided in the kit.

Conclusion:

The comparison between the predicate device and the proposed devices in section 12 of this submission demonstrates that the proposed devices are safe and effective, 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

JUN 13 2006

Mr. Christian Quass
Regulatory Affairs
Pajunk GmbH Medizintechnologie
Karl-Hall-Strasse 01
78187 Geisingen
GERMANY

Re: K060311
Trade/Device Name: EpiLong Sets for Anesthesiology, Anesthesia Conducting Catheter, LOR-Syringe, Flat Filter, Tuohy Borst Adaptor
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ, BSO
Dated: June 2, 2006
Received: June 5, 2006

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 (240) 276-3150 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

Indications for use

510(k) Number: **K060311**

Device Name: **EpiLong Sets for Anesthesiology**

Indications for Use:

The Pajunk **EpiLong** anesthesia conduction kit is indicated for administration of epidural anesthesia.

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

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Indications for use

510(k) Number: **K060311**

Device Name: **Anesthesia conducting Catheter**

Indications for Use:

The Pajunk catheter is placed in the epidural space to facilitate a longer anesthetic effect.

After the anesthesia conduction needle has been withdrawn from the patient, the catheter tip can remain in the epidural space for as long as determined by the professional anesthetist and the instructions for use (up to 72 hours).

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

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Indications for use

510(k) Number: **K060311**

Device Name: **LOR-Syringe**

Indications for Use:

The Pajunk Loss of Resistance (LOR)-Syringe is intended for use in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique as explained in standard medical textbooks.
These syringes are not intended for injection or aspiration.

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

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Indications for use

510(k) Number: **K060311**

Device Name: **Flat Filter**

Indications for Use:

The Pajunk anesthesia conduction flat filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

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

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Indications for use

510(k) Number: **K060311**

Device Name: **Tuohy Borst Adaptor**

Indications for Use:

The Pajunk Tuohy Borst Adaptor is connected to the needle via Luer connector. It ensures sealing and fixation of the catheter end and allows attachment of a Luer Lock syringe or infusion device.

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

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