

JUN 13 2006

K060311

EpiLong Premarket Notification Submission

MEDIZINTECHNOLOGIE

**510(k) Premarket Notification Submission:**

**Summary of Safety and Effectiveness**

**Date of Preparation: June 2006**

**Submitter Information/ production site:**

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**Contact:**

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E-Mail: [christian.quass@pajunk.com](mailto: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,

**Proposed 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**)

# EpiLong Premarket Notification Submission

MEDIZINTECHNOLOGIE

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## Device Description

Pajunk's **EpiLong** set is a single use, sterile, non-pyrogenic and latex free medical device kit. It is an 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 The cannula is then withdrawn, leaving the Epidural Catheter tip in the epidural space for as long as determined by the professional anesthetist and the instructions for use (up to 72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 equivalence 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



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.

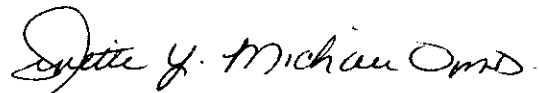
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

EpiLong Premarket Notification Submission



**Indications for use**

**510(k) Number:** K060311

**Device Name:** EpiLong Sets for Anesthesiology

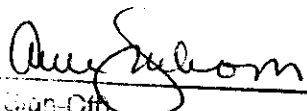
**Indications for Use:**

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Amy Salmon  
Department of Anesthesiology, General Hospital,  
Person Control, Dental Devices  
510(k) Number:   K060311



**Indications for use**

**510(k) Number:** K060311

**Device Name:** Anesthesia conducting Catheter

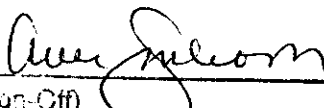
**Indications for Use:**

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Sign-Off)  
Department of Anesthesiology, General Hospital,  
Drug Control, Dental Devices  
Number   K060311



**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.

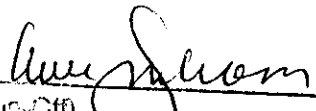
Prescription Use   **X**    
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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)

  
\_\_\_\_\_  
(Sign-Off)  
Department of Anesthesiology, General Hospital,  
Pain Control, Dental Devices  
Number   K060311







**Indications for use**

**510(k) Number:** K060311

**Device Name:** Tuohy Borst Adaptor

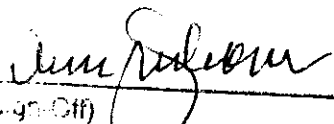
**Indications for Use:**

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)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Sign-Off)  
Dept of Anesthesiology, General Hospital,  
Device Control, Dental Devices  
Number:   K060311