K062902

JUN - 7 2007

PAJUNK®
MEDIZINTECHNOLOGIE

510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

Date of Preparation: May 2nd , 2007

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Contract Sterilizer:
Sterigenics Germany GmbH
FDA-ERN: 3002807090

Device Information:

Trade Names:	**Pajunks EpiLong Set Pediatric, EpiLong Soft Pediatric, EpiLong Pediatric Kit acc. Marhover**
Common Name:	Pediatric Epidural Anesthesia Sets Pediatric
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. Pajunks EpiLong Set **K060311**
2. Portex Pediatric Epidural and Peripheral Block Anesthesia Catheter **K033080**
3. MEDDEVICE´s BIO-MATE pediatric epidural catheter **K901129**
4. BBrauns PERIFIX pediatric epidural kit **K962696**

Device Description

Pajunk's **EpiLong Anesthesia Sets Pediatric** are single use, sterile, non-pyrogenic and latex free medical device kits for use with pediatric patients.
They are intended for continuous epidural anesthesia delivery using the Polyamide indwelling catheter. The catheter has to be removed or replaced after 72 hours.

The set is equipped with an epidural needle, for example the Tuohy. The Tuohy needle is a proven and established needle variant used in epidural anaesthesia.

PAJUNK® offers the catheters for pediatric use in different lenghts and diameters. The catheter itself is equipped with ascending depth graduations. With these depth graduations the position of the catheter can be exactly determined at any time. A marker at the end of the catheter indicates how deep the catheter can be introduced. Optionally the catheter can be employed with a stylet, an integrated spiral (called Epilong Soft Pediatric) or open tip.

Predicate Devices

The devices Pajunk claims substantial equivalence with is Pajunks **Epilong Set** cleared under **K060311,** BBrauns Perifix Pediatric epidural kit **K962696**, Portex´s Pediatric Epidural and Peripheral Block Anesthesia Catheter **K033080**, MEDDEVICE´s Bio-mate pediatric epidural catheter **K901129**.

The indication for use of Pajunks EpiLong Sets already cleared for market for an unspecified patient population is enhanced for pediatric patients.

The detailed discussion of substantial equivalence can be found in Section 12 of this submission. Because there is no change in technology or material the focus is set on the clinical literature review in section 10 of this submission.

Sterilization

Sterilization method: EtO

The contract sterilizer and the sterilizing process are identical to the ones used for all of Pajunks devices provided sterile, especially the anesthesia conduction devices cleared for the US market in several Premarket Notification submissions.

By annual validation and quarterly verification as well as by shelflife testing the sterilization procedure is claimed to be safe and effective for several years now.

Technology Characteristics:

The Pediatric epidural Anesthesia Set provides a standard epidural needle. Variant: The EpiLong Marhofer Kit. Within this Kit the needle is (NanoLine or lacqueur) coated.

The catheter comes with a catheter container introductory aid for better handling and shape security, a LOR syringe, a flat filter and a Tuohy Borst adaptor. The catheter is closed at tip and equipped with three lateral holes, optional with open tip, an integrated spiral (for enhanced stability) and a stylet. There is no change in components compared to the EpiLong sets already cleared for market.

All components are available seperately.

Conclusion:

The comparison between the predicate devices and the proposed devices in section 12.0 of this submission demonstrates that the proposed devices are at least as safe and effective as, and 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 - 7 2007

Mr. Christian Quass
Director Regulatory Affairs, Ass. Safety Official
PAJUNK® GmbH Medizintechnologie
Karl-Hall-Strasse 01
78187 Geisingen,
GERMANY

Re: K062902
Trade/Device Name: Pajunks EpiLong Sets Pediatric, Pajunk EpiLong Sets Pediatirc acc. Marhover, Pediatric Epidural Catheter, Pajunks Pediatric Epidural Needles
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: May 31, 2007
Received: June 04, 2007

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: **K062902**
Device Name: **Pajunks EpiLong Sets Pediatric**

Indications for Use:

The **Pajunk EpiLong Sets Pediatric** are intended for delivery of continuous conduction of epidural anesthesia. The catheter has to be removed or replaced after 72 hours.

They are to be used with pediatric patient population.

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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...vision of Anesthesiology, General Hospital,
...fection Control, Dental Devices

510(k) Number K062902

Indications for use

510(k) Number: K062902
Device Name: **Pajunks EpiLong Sets Pediatric acc. Marhover**

Indications for Use:

The **Pajunk EpiLong Sets Pediatric acc. Marhover** are intended for delivery of continuous conduction of epidural anesthesia. The Marhover-Set contains a NanoLine coated cannula. The catheter has to be removed or replaced after 72 hours.

They are to be used with pediatric patient population.

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

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...ection Control, Dental Devices

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Indications for use

510(k) Number: **K062902**
Device Name: **Pediatric epidural catheter**

Indications for Use:

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

It is intended for use with pediatric patients.

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. It has to be removed or replaced after 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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...ection Control. Dental Devices

...0(k) Number K062902

Indications for use

510(k) Number:
Device Name: **Pajunks Pediatric Epidural needles**

Indications for Use:

Pajunks pediatric epidural needles are anesthesia conduction needles e mployed to identify and to access epidural space.

It is intended for use with pediatric patients.

After epidural space is accessed and the catheter is inserted the anesth esia conduction needle has to be withdrawn from the patient.

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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K062902