K080675

Section 05

510(k) Summary of Safety and Effectiveness

JUN 20 2008

This section of the submission for **PAJUNK®'s InfiltraLong Wound infiltration catheter kit** contains

- The summary of safety and effectiveness
- Submitter Information
- Device Information
- Device Description
- Predicate devices
- Sterilization
- Technology Characteristics
- Safety and Effectiveness: Conclusion

The 510(k) Summary may be copied and submitted to interested parties as required by 21 CFR 807.92.

510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

Date of Preparation: June 6th 2008

Submitter Information/ production site:
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Establishment Registration Number: **9611612**

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30084 Tucker, Georgia
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Contact
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E-Mail: stefan.dayagi@pajunk-usa.com

Contract Sterilizer:
STERIGENICS GERMANY GMBH
Rheingaustrasse 190-196
65203 Wiesbaden, GERMANY
Registration Number: 3002807090
Operations: Contract Sterilizer

Device Information:

Device/ Trade Name:	**InfiltraLong Wound infiltration catheter, Pain Management**
Common Name:	**Anesthesia conduction catheter**
Classification Name:	**Catheter, conduction, anaesthetic**
Classification Reference:	**21CFR 868.5120**
Establishment Registration Number:	**9611612**
Regulatory Class:	**II**
Product Code:	**BSO**
Subsequent product code	**MRZ**
Subsequent Classification Reference:	**21CFR880.5725**
Panel:	**Accessories, Pump, infusion**
Predicate Devices	**General Hospital** 1. **K022869** Soaker catheter (I-Flow, On-Q) 2. **K051401** Soaker catheter (I-Flow, On-Q)

Device Description: Indications for use

PAJUNK®'s Wound Infiltration Catheter Kit called InfiltraLong is intended for continuous or intemittent praeoperative, perioperative or post-operative delivery of local anesthetics or narcotlcs to wounds and surgical wound sites. Routes of adrninistration may be intraoperative or percutaneous. The sterile components are available seperately.

Contraindications: Intravascular and intra-arterial-, as well as application in the vicinity of the spinal cord. Application of liquids which are not analgesics. Draining of wound fl uid.

Complications: Systemic toxicity of the local anaesthetics used (observe dosage!), infection. The contraindications and complications in accordance with medical literature corresponding to the state of education shall also apply. The placement of the catheter should, as a rule, not exceed 72 hours due to the increased risk of infection.

Predicate Devices:

Predicate devices with identical or at least similar indications for use are:

1. **K022869 Soaker catheter (I-Flow, On-Q)**
2. **K051401 Soaker catheter (I-Flow, On-Q)**

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

The components are cleared in PAJUNK®'s own 510(k)'s (e.g. K040965, K013041, K063697, K060563) for use in regional anaesthesia and to be used contacting cerebrospinal fluid.

Sterilization and Packaging

The contract sterilizer and the process of sterilization is the same as it is used for all PAJUNK®- Products already cleared for market. The contract sterilizer is monitored by FDA and listed in the FDA database for sterilization services. The process complies with DIN EN ISO 11135 *Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.*
The packaging is identical to the packaging of PAJUNK®'s kits for regional spinal and epidural anaesthesia already approved for being marketed in the US.

Technology Characteristics:

The kit is available in two basic designs:

Design 02	Design 01
• Coiled catheter (1x/ 2x) • Y-connector • FixoLong Catheter fixation device • Adapter • Puncture needle • Permanent teflon cannula • Flat filter	• Coiled catheter (1x/ 2x) • Y-connector • FixoLong Catheter fixation device • Adapter • Tear-cannula (also referred to as Split-cannula) • Flat filter

Bench Testing

The catheter complies with ISO10555 *Sterile, single-use intravascular catheters* and EN1618 *Catheters other than intravascular catheters - Test methods for common properties.* The needles comply with ISO7864, ISO594 and ISO9626.

Conclusion:

The comparison between the predicate devices and the proposed devices in section 12 of this submission as well as the validated sterilization process and the results of the bench testing 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2008

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

Re: K080675
Trade/Device Name: PAJUNK Wound Infiltration Catheter Kit, InfiltraLong
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO, MRZ
Dated: May 1, 2008
Received: May 7, 2008

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.

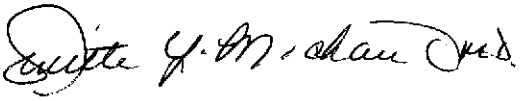
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for use

510(k) Number:

Device Name: **PAJUNK®'s Wound Infiltration Catheter kit, InfiltraLong**

Indications for Use:

PAJUNK®'s Wound Infiltration Catheter Kit called InfiltraLong is intended for continuous or intemittent praeoperative, perioperative or post-operative delivery of local anesthetics or narcotics to wounds and surgical wound sites. Routes of adrninistration may be intraoperative or percutaneous.

The sterile components are available seperately.

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: K080675