K082164

PAJUNK
MEDIZINTECHNOLOGIE

510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

Date of Preparation: July 21st 2008

OCT 27 2008

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

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Contract Sterilizer:
1) Sterigenics Germany GmbH
2) HA2 Halberstadt

Device Information:

Device Name:	**PAJUNK®'s Generic Convenience Tray for Regional Anesthesia of the peripheral plexus**
Trade Names:	**StimuLong, PlexoLong, Sono, Several generic, e. g. Basis Set, Spinal Set, Customer Set**
Common Name:	**Convenience Tray for Regional Anesthesia**
Classification Name:	**Kit, conduction anesthesia**
Classification Reference:	**21CFR868.5140, revised April 1st 2007**
Establishment Registration Number:	**9611612**
Regulatory Class:	**II**
Product Code:	**CAZ**
Panel:	**Anesthesiology**
Predicate devices	**K053283 NanoLine** **K013041, K023218, K042979 PlexoLong** **K033018, K043130 StimuLong** **K062900 StimuLong Tsui Method, StimuLong Sono**

Device Description:

The convenience tray subject to this submission is compiled by customers from devices either cleared by FDA in former 510(k) submissions or exempt to 510(k) clearance procedure. It may contain each one of PAJUNK®'s devices cleared for use in Anaesthesia of the peripheral plexus procedures. The tray complies with FDA´s guidance "Sterilized convenience kits".

The devices made available for this tray are listed in section 11 of this submission.

Predicate Devices:

Predicate devices with identical or at least partial indications of use are:

1. K053283 NanoLine
2. K013041, K023218, K042979 PlexoLong
3. K033018, K043130 StimuLong
4. K062900 StimuLong Tsui Method, StimuLong Sono

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

Sterilization

The contract sterilizer and the sterilizing process is the same as used for all PAJUNK®-manufactured and purchased devices which are already cleared for market or exempt and which may be contained in a convenience tray.

Sterilization method, which ensures an SAL of 10^{-6} as well as limits for bioburden, pyroburden (i. e. LAL) and EtO-residuals and shelf life have been validated and are safe and effective. Efficacy of sterile product´s lifecycle has been proven for a periode of 10 years now. Shelf life is set to 5 years.

Biocompatibility

All devices comply with ISO 10993-1, FDA-modified version also.

Technology Characteristics:

The components are listed in a table in section 11 of this submission. Shelf life and impact of sterilization and storage on the devices has been proven and found to be safe and effective.

Conclusion:

The comparison between the predicate devices and the proposed devices in section 12 of this submission as well as the validated sterilization process demonstrates that the proposed devices are substantially equivalent to the predicate devices and safe and effective.

The tray components are marketed in similar combinations in Europe for more than ten years now and are safe and effective. Efficacy of manufacturing, tray assembly, sterilization, storage and shelf life has been proven.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Christian G. H. Quass
Director Regulatory Affairs
PAJUNK® GmbH Medizintechnologie
Karl-Hall-Strasse 01
78187 Geisingen
GERMANY

OCT 27 2008

Re: K082164
Trade/Device Name: PAJUNK®'s Generic Convenience Tray for Regional Anesthesia of the Peripheral Plexus Continuous
PAJUNK®'s Generic Convenience Tray for Regional Anesthesia: Common Procedure Supply
PAJUNK®'s Generic Convenience Tray for Regional Anesthesia of the Peripheral Plexus
PAJUNK®'s Generic Convenience Tray for Regional Anesthesia of the Peripheral Plexus: Single Shot

Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: July 29, 2008
Received: July 31, 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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

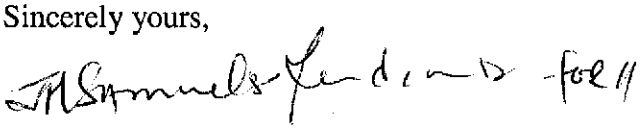
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 the labeling regulation, please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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.dsma/dsmamain.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

PAJUNK
MEDIZINTECHNOLOGIE

Indications for use

510(k) Number:

Device Name: **PAJUNK®'s Generic Convenience Tray for Regional Anesthesia of the peripheral plexus continuous**

Indications for Use:

PAJUNK®'s Generic Convenience Tray for Regional Anesthesia of the peripheral plexus continuous is intended for the administration of regional anaesthesia to the peripheral plexus employing continuous technique via catheter, also including optional localization via electrical stimulus.

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

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Indications for use

510(k) Number:
Device Name: **PAJUNK®'s Generic Convenience Tray for Regional Anesthesia: Common Procedure supply**

Indications for Use:

PAJUNK®'s Generic Convenience Tray for Regional Anesthesia: Common Procedure supply is intended to *support* the administration of regional anaesthesia. Neither needle nor catheter is included.

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

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Infection Control, Dental Devices

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Indications for use

510(k) Number:
Device Name: **PAJUNK®'s Generic Convenience Tray for Regional Anesthesia of the peripheral plexus**

Indications for Use:

PAJUNK®'s Generic Convenience Tray for Regional Anesthesia is intended for the administration of regional anaesthesia to the peripheral plexus, single-shot or continuous technique, optional localization via electrical stimulus.

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

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Infection Control, Dental Devices

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Indications for use

510(k) Number:
Device Name: **PAJUNK®'s Generic Convenience Tray for Regional Anesthesia of the peripheral plexus: single shot**

Indications for Use:

PAJUNK®'s Generic Convenience Tray for Regional Anesthesia of the peripheral plexus single shot is intended for the administration of regional anaesthesia to the peripheral plexus employing single-shot technique also including optional localization via electrical stimulus.

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

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