PAJUNK
MEDIZINTECHNOLOGIE

510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

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Date of Preparation: July 10th, 2006

AUG 31 2006

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Establishment Registration Number:

9611612

Device Information:

Trade Names: **Pajunk RFTL Radiofrequency needle**

Common Name: Disposable cannula for RF Thermolesion

Classification Name: Neurological Devices: Radiofrequency lesion probe

Classification Reference: 21 CFR 882.4725, April 1. 2005

Poposed Classification: Regulatory Class II

Proposed Product Code: GXI

Predicate Devices:
1. Radionics thermo lesion needles **K021942**
2. Stryker's RF cannulas **K032406**

Device Description:

Pajunk RFTL Radiofrequency needles are intended for coagulation of soft tissues, such as in long term pain treatment via neurosurgical lesioning procedures, as determined by professional neurosurgeon/ anesthetist and the instructions for use. These RF-cannulas are single use, sterile, non-pyrogenic and latex free medical devices. The RF-cannulas have bevel tips with an active area of 2 – 10 mm.

The needle puncture depth depends on the path chosen by the surgeon to reach and to eliminate the nerve bundle site. This required needle length is the patient contact part of the thermolesion needle. The nerve causing constant pain will be disrupted by utilizing the thermolesion heat radiating from the needle tip. Heat is generated by radio frequency and radiates only from the non-insulated needle tip. This limited heat radiation is used for focussed heat treatment depending on the surgeon's method of operation.

Predicate Devices

Pajunk's single use anesthesia conduction needles for thermo lesion and neuro-stimulation are substantially equivalent in technique, specification, intended use, safety and effectiveness to the marketed predicate device listed above.

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 Unipolar cannulas cleared for market by FDA under 510(k) number **K000722** and Kit Products Pajunks Stimulong Set **K043130, K033018** and Pajunks Plexolong Set **K042979, K023218, K013041.**

Packaging

The packaging materials and procedures of Pajunk's **RFTL cannulas** are the same as those used for Unipolar cannulas cleared for market by FDA under 510(k) number **K000722** and Kit Products Pajunks Stimulong Set **K043130, K033018** and Pajunks Plexolong Set **K042979, K023218, K013041.**

Technology Characteristics

The indications for use as well as the basic technological characteristics of Pajunk's **RFTL cannulas** are identical to Radionics thermo lesion needles **K021942** manufactured by TOP. Coating, overall cannula lenght and lenght of deinsulated tip are substantially equivalent and as safe and effective as the predicate device´s.

Pajunk's **RFTL cannulas** have the same technological characteristics as the predicate device identified above.

The NanoLine coating technique Pajunks cannulas are coated with is cleared for market in Pajunks NanoLine PMN **K053283**.

Conclusion:

The comparison between the predicate devices and the proposed devices 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

AUG 31 2006

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

Re: K060397
Trade/Device Name: Pajunk Thermolesion Cannula „RFTL Radiofrequency Needle"
Regulatory Number: 21 CFR 882.4725
Regulatory Name: Radiofrequency lesion probe
Regulatory Class: II
Product Code: GXI, GXD
Dated: July 31, 2006
Received: August 3, 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) 276-0115. 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number: K060397

Device Name: **Pajunk Thermolesion Cannula „RFTL Radiofrequency Needle“**

Indications for Use:

Pajunk RFTL Radiofrequency needles are electrically insulated (with lacquer or NanoLine) Cannulas, which may be used either for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning. The nerve is localized either by using electrical neuro-stimulation through the needle or by injecting contrast medium through the needle and using radiography concomitantly. The nerve may then be blocked by injecting local anesthetic or a radiofrequency lesion may be made.

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 General, Restorative,
and Neurological Devices

510(k) Number K060397

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