K061172

Section 6.0

510(k) Summary of Safety and Effectiveness

This section contains the 510(k) Summary of Safety and Effectiveness.
(This document can be copied and submitted to interested parties as required by 21CFR 807.92).

510(k) Summary of Safety and Effectiveness

Submitter's Information:

OCT 17 2006

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USA
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Device Name:

Trade Names: MultiStim SENSOR

Common Names: Peripheral Nerve Stimulator

Classification Name: Electrical Peripheral Nerve Stimulator (Reference, 21 CFR, 868.2775)

Product Class: Class II

Product Code: KOI

Predicate Devices:

Pajunk's MultiStim SENSOR Nerve Stimulators are substantially equivalent to Pajunk's MultiStim VARIO Nerve Stimulators marketed under 510(k) number K011308.

Device Description:

The MultiStim SENSOR devices are hand-held, battery-driven peripheral nerve stimulators for this purpose. The devices can be used for:

- Nerve finding with peripheral nerve stimulation needles
- Percutaneous localization

In relaxation monitoring for general anesthesia, the peripheral nerve stimulation technique is used to interpret the muscular feedback to stimulation pulses applied through adhesive skin electrodes in regards to the level of muscle relaxing drugs in the patient. Special functions do support this. Due to the fact, that the stimulation is done through the skin, much more electrical power is needed. That's why a stimulation current range of 0-60mA is needed.

In both applications, negative, monophasic pulses are to be generated by the devices and applied to humans either through peripheral nerve stimulation needles or through self-adhesive stimulation electrodes on the skin. Since the human body acts as a variable resistor and the anesthesiologist sets the device to a certain stimulation current, the nerve stimulator has to act as a constant-current-source. A built in microprocessor constantly adapts the voltage applied to the patient in order to compensate the varying patient's resistance and to provide a constant current through the patient.

Intended Use:

Pajunks's MultiStim SENSOR is intended for nerve stimulation during anaesthesia delivery; first for percutaneous identification of peripheral nerves and second for percutaneous localizations. This device is indicated for adults only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2006

Pajunk GmbH Medizintechnologie
C/O Ms. Lynette L. Howard
Lyle Howard Corporation
106 East 5th Avenue
Mount Dora, Florida 32757

Re: K061172
Trade/Device Name: Pajunk Anesthesia MultiStim SENSOR-Nerve Stimulators
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: September 22, 2006
Received: September 26, 2006

Dear Ms. Howard:

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 (if known):

Device Name: **Pajunk Anesthesia MultiStim SENSOR – Nerve Stimulators**

Indications For Use:

Pajunks's MultiStim SENSOR is intended for nerve stimulation during anaesthesia delivery; first for percutaneous identification of peripheral nerves and second for percutaneous localizations. This device is indicated for adults only.

Prescription Use X AND/OR Over-The-Counter Use ______
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Replacement for original pages 8 & 27

...on Sign-Off
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number: K061172