DEC 21 2004

K042979

510(k) Summary of Safety and Effectiveness

Submitter Information:

PAJUNK GmbH
Karl Hall Straße 1
D78187 Geisingen
Germany

USA Contact:

Mr. Burk A. Brandt
CE Consultancy, Inc.
5010 NW Crescent Valley Dr.
Corvallis, OR 97330 – USA
Phone: (541) 752-3953
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Device Name:

Trade Name: Plexalong Sets
Common Name: Anesthesia Conduction Kit
Classification Name: Anesthesia Conduction Kit (Reference, 21CFR, 868.5140, April 1, 2003), Anesthesia Conduction Needle (Reference, 21CFR, 868.5140, April 1, 2003)

Predicate Devices:

Plexalong sets consist of a Pajunk Unipolar needle (conduction cannula with nerve stimulus connector and tubing), stylet, and an open end catheter and a catheter adapter. The Plexalong sets have been cleared under K013041 and the Unipolar needles under 510(k) number K000722 (facet and Sprotte tip conduction cannula and tubing). Unipolar needles with a Tuohy tip were cleared for market under 510(k) number K023218.

The packaging materials used to package the Pajunk Plexalong sets, and needles have not changed. The contract sterilizer, other than a company name change (was Griffith Micro Science, now Sterigenics) and sterilizing process is the same.

Device Description:

The Pajunk Plexalong sets are single use, sterile, non-pyrogenic and latex free conduction anesthesia sets intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. The Plexalong sets consist of a single use sterile, non-pyrogenic conduction needle with tubing, stilett, a catheter and catheter adapter. The stylet is used to stop tissue from clogging the needle (during insertion) by blocking the opening at the tip of the needle. Pajunk changed the stilett material from a surgical stainless steel to polycarbonate. The Unipolar needles used in the Plexalong sets are available in three tip configurations. A Unipolar needle with a facet tip, Sprotte tip or Unipolar needle with a Tuohy tip. Only Plexalong sets with the Tuohy needles are affected by the stilett material change. To assist the physician pinpoint the area of application, an electrical stimulus can be applied to the tip of the conduction needle via a nerve stimulus connector.

Intended Use:

The Pajunk Plexalong Sets are intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. Continuous delivery for up to 72 hours is accomplished using the Polyamide indwelling catheter. An electrical stimulus may be applied to the conduction needle via a cable and connectors to assist the physician pinpoint the area of application.

Technology Characteristics:

The Pajunk conduction needles, including the physical dimensions, connector, tubing, metal and plastics, have been cleared under 510(k) numbers K000722, K013041, K023218, and K033018. The material used to manufacture the Pajunk catheter and catheter adapter are identical to the materials used to manufacture the catheter and catheter adapter of the predicate devices described earlier in this *510(k) Summary of Safety and Effectiveness.* The Plexalong Sets are supplied in polypropylene containers that are sealed to assure sterility.

Summary of Performance Testing

The Pajunk Plexalong Sets were designed to conform to the applicable sections of the following recognized consensus standards. The testing included verifying conformance to these standards.

Standard	Issue Date	Title
DIN 13090/ISO 594	08.1984	Luer fittings w/wo locking feature
DIN 13097 Part 1	01.1980	Medical injection cannula
DIN 13097 Part 3	11.1979	Medical cannula
DIN 17442/ISO 9626	10.1977	Steel for medical instruments
DIN EN 550	07.1993	Sterilization of med. Prod.; Validation & routine controls for sterilization with ETO
DIN EN 556	01.1995	Sterilization of medical products, requirements for medical products that are labeled "sterile"
DIN EN 724	12.1994	Guidance on the application of EN29001 and EN46001 for non-active medical products
PrEN 868-1	10.1996	Packaging materials for the sterilization of packaged goods. Part 1: general requirements for the validation of the packaging of sterilized end-packaged products
DIN EN 868-2	03.1993	Packaging materials for the sterilization of packaged goods. Part 2: sterilization packaging, requirements and tests.
DIN EN 980	08.1996	Graphic symbols for marking medical products
DIN EN 1441	08.1994	Risk analysis for medical products
EN ISO 14971	2000	Risk Management
DIN EN 1707	01.1997	6% Luer cone connections for injection cannula and particular medical equipment
DIN EN/ISO 9626 and A1:2001	06.1995	Cannula tube of non-rusting steel (SS) for the manufacture of medical products
BS 6196	1889	Sterile epidural catheters and introducer needles for single use
DIN EN 30993-1	12.1994	Biological evaluation of medical products – instructions for selection of tests
DIN EN 46001	12.1993	Particular requirements for medical products
DIN 17440	09.1996	Stainless Steels
BS 4843		Single entry IV cannula

Conclusion:

The PAJUNK Plexalong Sets are as safe and effective as the predicate devices when used according to the instructions in the directions for use supplied with the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2004

PAJUNK GmbH
C/O Mr. Burk A. Brandt
CE Consultancy, Incorporated
5010 NW Crescent Valley Drive
Corvallis, Oregon 97330

Re: K042979
Trade/Device Name: Pajunk Plexalong Sets
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: December 4, 2004
Received: December 7, 2004

Dear Mr. Brandt:

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.

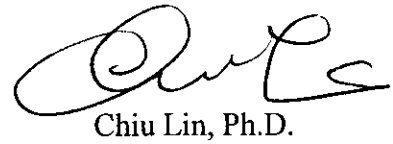
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Enclosure

INDICATIONS FOR USE

510(k) Number: K042979

Device Name: Pajunk Plexalong Sets

Indications for use:

The Pajunk Plexalong Sets are intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. Continuous delivery for up to 72 hours is accomplished using the Polyamide indwelling catheter. An electrical stimulus may be applied to the conduction needle via a cable and connectors to assist the physician pinpoint the area of application.

Warning:
The Pajunk GmbH needles and puncture sets are not intended for RF ablation or any other type of ablation procedure

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use XX OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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