K023210

MAR 2 4 2003

510(k) Summary of Safety and Effectiveness

Submitter Information:

PAJUNK GmbH
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78187 Geisingen
Germany

USA Contact:Mr. Burk A. Brandt
CE Consultancy, Inc.
5010 NW Crescent Vly Dr
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Phone: (541) 752-3953
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Device Name:

Trade Name: Plexolong Sets
Common Name: Anesthesia Conduction Kit
Classification Name: Anesthesia Conduction Kit (Reference, 21CFR, 868.5140, April 1, 2000)

Predicate Device:

These Plexus Anesthesia sets consist of a Pajunk Touhy needle (with nerve stimulus connector and Luer lock), tubing (with Luer locks)), catheter (with Teflon coated stylet), catheter adapter and filter. The set, including the packaging is identical to the Plexolong Sets cleared for market under 510(k) number K013041, except for the Touhy needles with nerve stimulus connector. The Touhy needle is identical to the Unipolar needle, included in these sets, except for the shape of the needle tip. The Touhy needle tip configuration is same as the B Braun Touhy needle, cleared for market under 510(k) number K813186 as referenced in their submission number K013610.

The intended use statement, except for a reference to the Tuohy needle, is identical to the intended use statement in K013041. Except for the shape of the needle tip, the materials, construction and manufacturing processes are also identical to the cleared Pajunk Anesthesia Sets.

The contract sterilizer and sterilizing process are identical to those used for the Pajunk Plexolong sets. The packaging materials are also the same as those used to package the Pajunk previously cleared Plexolong sets.

Device Description:

The PAJUNK Plexolong sets contain single use sterile and non-pyrogenic needles with tubing, with or without a plastic cannula and catheters intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. Continuous delivery is accomplished using the catheter. An electrical stimulus may be applied to the conduction needle via a cable and connector to assist the physician pinpoint the area of application.

Intended Use:

The PAJUNK Plexolong sets consist of Pajunk Unipolar conduction needle with a plastic cannula placed over the needle, or a Tuohy conduction needle. They 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 connector 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.

Technology Characteristics:

The PAJUNK Unipolar needles, which include the physical dimensions, coating, connector, tubing, metal and plastics, have been cleared under 510(k) number K000722. The Touhy needle is identical to the Unipolar needle, included in these sets, except for the shape of the needle tip. The Touhy needle tip configuration is same as the B Braun Touhy needle, cleared for market under 510(k) number K813186 as referenced in their submission number K013610.The Plexolong Sets are supplied in sealed polypropylene containers or polypropylene and styrol paper envelopes that are sealed to assure sterility.

Summary of Performance Testing:

The PAJUNK Plexolong 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
DIN EN 1707	01.1997	6% Luer cone connections for injection cannula and particular medical equipment
DIN EN/ISO 9626	06.1995	Cannula tube of non-rusting steel (SS) for the manufacture of medical products
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 Plexolong 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

MAR 2 4 2003

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

Re: K023218
Trade/Device Name: Pajunk Plexolong Sets
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ, BSP
Dated: February 25, 2003
Received: February 27, 2003

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 (301) 594-4646. 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,

Susan Runner

Susan Runner, DDS, MA
Interim 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: ___K023218____

Device Name: Pajunk Plexolong Sets

Indications for use:

The Pajunk Plexolong 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 ✓ or Over-The- Counter_____
(Per 21 CFR 801.109)

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

510(k) Number: K023218