JUN 11 2002

K013041

510(k) Summary of Safety and Effectiveness

Submitter Information:

PAJUNK GmbH
AM Holzplatz 5-7
78187 Geisingen
Germany

USA Contact: Mr. Burk A. Brandt
CE Consultancy, Inc.
5010 NW Crescent Vly Dr
Corvallis, OR 97330 – USA
Phone: (541) 752-3953
Fax : (541) 752-3972

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:

The Plexus Anesthesia sets consist of a Pajunk Unipolar needle (with nerve stimulus connector and tubing), a plastic cannula, front-end open tip catheter with Teflon coated stylet and catheter adapter. The Unipolar needles (with nerve stimulus connector and tubing) have been cleared for market by the FDA under 510(k) number K000722.

The plastic cannula, front-end open tip catheter with Teflon coated stylet and catheter adapter are substantially equivalent to the plastic cannula, catheter with stylet and catheter adapter contained in identical sets manufactured by B Braun Medical Inc. that were cleared by the Food and Drug Administration under 510(k) number K840287.

The contract sterilizer and sterilizing process are identical to those used for the Pajunk Unipolar needles. The packaging materials are also the same as those used to package the Pajunk Unipolar needles. The difference is that the packaging is slightly larger to accommodate the plastic cannula, catheter with stylet and catheter adapter.

Device Description:

The PAJUNK Plexolong sets are single use sterile, Latex free and non-pyrogenic needles, with a plastic cannula and catheter intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. 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.

Intended Use:

The PAJUNK Plexolong sets consist of Pajunk Unipolar conduction needle with a plastic cannula placed over the 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 material used to manufacturer the Pajunk catheter and catheter adapter are identical to the material used to manufacture the catheter and catheter adapter of the predicate device described earlier in this *510(k) Summary of Safety and Effectiveness.* The Plexolong Anesthesia Sets are supplied in sealed polypropylene containers or polypropylene and styrol paper envelopes that are sealed to assure sterility.

Conclusion

The Pajunk Plexolong Anesthesia Sets are as safe and effective as the predicate device when used in accordance with the instructions supplied with the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2002

Pajunk GmbH
Mr. Burk A. Brandt
c/o CE Consultancy, Inc.
5010 NW Crescent Valley Drive
Corvallis, OR 97330

Re: K013041
Plexolong Sets
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II (two)
Product Code: CAZ
Dated: June 5, 2002
Received: June 6, 2002

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.

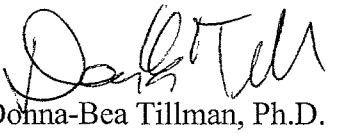
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K013041

Device Name: Pajunk Plexalong Anesthesia Sets

Intended Use:

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter _____

(Per 21 CFR 801.10)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013041