K053282

Special 510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

Date of Preparation: October 27, 2005

Submitter Information/ production site:

Pajunk GmbH
Karl-Hall-Straße 01
78187 Geisingen
Germany
Fon: +49(0)7704-9291-0
Fax: +49(0)7704-9291-610

Contact:

Christian Quaß, Regulatory Affairs
Fon: +49(0)7704-9291-533
Fax: +49(0)7704-9291-605
E-Mail: christian.quass@pajunk.com

Device Information:

Trade Names:	Monopolar Electrodes with Ceramic Tip
Common Name:	**Monopolar Electrodes**
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Reference:	21 CFR 878.4400, April 1. 2005
Poposed Classification:	Regulatory Class: II
Proposed Product Code:	GEI
Predicate Devices:	1. Pajunk's monopolar electrodes marketed under **K033249** 2. Aesculap's modular monopolar ceramic tip electrodes **K970541**

Device Description:

The Pajunk ceramic tip electrodes are multiple uses, non-sterile delivered and latex free medical devices. They are intended for transient delivery of energy required for coagulation of tissue.

The Pajunk MIC-System contains but is not limited to HF-electrodes for comfortable and safe coagulation. Pajunk provides electrodes with and without suction and irrigation element and electrodes with suction and irrigation capacity with retractable/ extendable tips. Isolation at tip is made by ceramic.

The Modular system for optional monopolar coagulation enables a surgeon to manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures. The instruments are insulated for optional monopolar coagulation.

The electrode-tips are retractable for comfortable suction and irrigation performance.

The Pajunk ceramic tip electrodes are intended for transient delivery of energy required for coagulation of tissue. Ceramic tip electrodes are used during minimal invasive surgery, according to the professional surgeon and the instructions for use. The ceramic tip electrodes consist of a medical grade steel tube, ceramic tip and stainless steel electrode tip.

Technology Characteristics:

Pajunk's monopolar ceramic tip electrodes have the same technological characteristics as the predicate device identified below.

Pajunk's monopolar ceramic tip electrodes are substantially equivalent to Pajunk's monopolar electrodes marketed under 510(k) number **K033249**. All materials, dimensions and intended use are identical. There is one exception, which is the electrical insulation at the electrode tip. The polyamide (Nylon) coating is substituted by a ceramic tip.

Pajunk's monopolar ceramic tip electrodes are equivalent in design, physical dimensions, ceramic, metal and plastics materials, to Aesculap's monopolar ceramic tip electrodes marketed under 510(k) number **K970541**.

There is one design difference: Aesculap's monopolar ceramic tips can be unlocked from the electrode shaft. Pajunk's monopolar ceramic tips are fixed to the electrode shaft and can not be removed, nor lost during a surgical procedure.

Biocompatibility testing of Pajunk's monopolar ceramic tip electrodes is located in Section 7 of this submission.

Conclusion:

The comparison between the predicate device and the proposed device demonstrates that the proposed device is safe and effective, as well as substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2005

I. A. Christian Quass
MA Regulatory Affairs
Pajunk GmbH
Karl-Hall-StraBe 01
78187 Geisingen
Germany

Re: K053282
Trade/Device Name: Pajunk ceramic tip electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Eye pad
Regulatory Class: II
Product Code: GEI
Dated: November 21, 2005
Received: November 25, 2005

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.

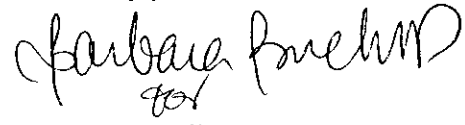
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting 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: K053282

Device Name: **Pajunk ceramic tip electrodes**

Indications for Use:

Ceramic tip electrodes are used during minimal invasive surgery, according to the professional surgeon and the instructions for use.

Ceramic tip electrodes are instruments insulated for optional monopolar coagulation which enable a surgeon to grasp, manipulate, dissect, retrieve, biopsy, cut or coagulate internal tissue or organs while performing laparoscopic procedures.

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)

Barbara Buelow for MPM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053282