K060808

JUL 25 2006

510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

Date of Preparation: July 20th, 2006

Submitter Information/ production site:

Pajunk GmbH Medizintechnologie
Karl-Hall-Strasse 01
78187 Geisingen
Germany
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605

Contact:

Christian Quass, Regulatory Affairs
Fon: +49(0)7704-9291-586
Fax: +49(0)7704-9291-605
E-Mail: christian.quass@pajunk.com

Contract Sterilizer:

SteriPro Lab & EO Facility
Dreieichstrasse. 7
64546 Moerfelden
Germany
Tel +49 6105 23091 or +49 (0) 6105 93470
Fax +49 6105 24760

Establishment Registration Number:

9611612

Device Information:

Trade Names:	BrainPro, Brain Pro Access
Common Name:	Cannula for brain biopsy, Brain biopsy needle and accessory
Classification Name:	Stereotaxic instrument
Classification Reference:	21 CFR §882.4560, April 1, 2005
Poposed Classification:	Regulatory Class II
Proposed Product Classification Code:	HAW
Panel:	Neurology
Predicate Devices:	1. Radionics Nashold Biopsy needle – Single use **K032054** 2. Ad-Tech Medical Instrument Corporation **K924348** 3. Field Lee Brain Biopsy needle **K801760**

Device Description:

The Pajunk **BrainPro** biopsy cannula is a single-use device intended for use in navigational guided biopsy of brain tumors.

The Pajunk **BrainPro** Biopsy Needle is a singel use dual cannula device made from stainless steel or titanium. The cannula requires vacuum suction provided by a syringe to draw the tissue into the needle. The inner cannula is then rotated to cut the tissue.

The Pajunk **BrainPro Access** is a single-use anchoring and guidance instrument for Pajunks BrainPro biopsy cannula with cutting titanium thread for drill holes.

Predicate Devices:

- Radionics Nashold Biopsy needle – Single use **K032054**
- Ad-Tech Medical Instrument Corporation **K924348**
- Field Lee Brain Biopsy needle **K801760**

The detailed discussion of substantial eqivalence can be found in Section 12 of this submission.

Sterilization

The contract sterilizer and the sterilizing process other than a company name change (was IBA Griffith Micro Science, and now is Sterigenics) is the same as that used for all Pajunk devices already cleared for market, most of them similar in technology and material to the BrainPro Set.

Technology Characteristics:

Pajunk's BrainPro cannula for brain biopsy with or without the BrainPro Access fixation device is a single use, sterile, non-pyrogenic and latex free medical device kit for brain biopsy.

The special cutting construction of the cannula enables sufficient biopsy material to be removed for a histological examination.

The BrainPro has proven equipment compatibility with the BrainLab Image guided surgery system VectorVision Cranial cleared by FDA under K020631 (see executive summary section 10.0 of this submission).

Conclusion:

The comparison between the predicate devices and the proposed devices in section 12 of this submission demonstrates that the proposed devices are safe and effective, as well as substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pajunk GmbH Medizintechnologie
% Christian Quass
Regulatory Affairs
Karl-Hall-Strasse 01
78187 Geisingen, Germany

JUL 25 2006

Re: K060808
Trade/Device Name: BrainPro cannula and BrainPro Access anchoring device for brain biopsy
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: June 19, 2006
Received: June 22, 2006

Dear Christian 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
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:

Device Name: BrainPro cannula and BrainPro Access anchoring device for brain biopsy

Indications for Use:

The Pajunk **BrainPro** biopsy cannula for brain biopsy is a single-use device intended for use in stereotactic and other guided biopsy of brain tissue, for example brain tumors. The BrainPro is provided in a set.

The Pajunk **BrainPro** Biopsy Needle is a dual cannula device made from stainless steel or titanium. The cannula requires vacuum suction provided by a syringe to draw the tissue into the needle. The inner cannula is then rotated against the outer cannula to cut the tissue.

The Pajunk **BrainPro Access** is an optional single-use anchoring and guidance instrument for Pajunks **BrainPro** biopsy cannula with cutting titanium thread for drill holes. It is used in brain biopsy procedures. The **BrainPro Access** is provided sterile.

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)

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

510(k) Number K060808