AD-TECH MEDICAL INSTRUMENT CORPORATION

APR 2 4 2012

K112094 510(k) Summary

This summary is provided to support the 510(k) notification for the Brain Biopsy Needles – MRI Conditional Product Family, manufactured by Ad-Tech Medical Instruments Corporation.

Company Name:	Ad-Tech Medical Instruments Corporation
Address:	1901 Williams Street Racine, WI 53404
Phone:	(262) 634-1555
Date Summary Prepared:	April 16, 2012
Trade Name:	Brain Biopsy Needle
Common Name:	Biopsy Instrument
Classification Name:	21 CFR 876.1075 Biopsy Instrument 21 CFR 882.4560 Stereotaxic Instrument
Predicate Devices:	510(k) Number: K924348 Trade Name: Brain Biopsy Needle Manufacturer: Ad-Tech Medical Instrument Corporation 510(k) Number: K990278 Trade Name: NeuroCut NeuroBiopsy Needle Manufacturer: Daum Corporation 510(k) Number: K060808 Trade Name: BrainPro Manufacturer: Pajunk GmbH Medizintechnologie

5.1 Product Description

Brain Biopsy Needles are used to remove a targeted sample of brain tissue for analysis. These Brain Biopsy Needles are side-cutting needles. Side-cutting needles can extract several tissue samples without requiring a new trajectory.

Biopsy needles are used to sample brain tissue or to extract brain tissue samples to determine tissue abnormality or any deviation from healthy brain tissue. These Brain Biopsy Needles substantially consist of two cannulae that fit inside one another. Both cannulas have a sampling window opening in the distal tip. The inner cannula window opening has a sharp edge. The Brain Biopsy Needle is placed into tissue to the desired depth. An aspiration syringe may be attached to the tip of the brain biopsy to support aspiration of a small amount of tissue into the sampling window. The inner cannula is rotated such that the sampling window removes a tissue sample. The inner cannula is removed. The tissue sample from the inner cannula is removed for analysis. The inner cannula may be passed back through the outer cannula and additional biopsies can be taken as directed by the surgeon.

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K112094

By this submission, the MDBM-08-28 Brain Biopsy Needle variation was confirmed meeting conditions to support labeling as "MRI Conditional". The Model MDBN-08-28 Brian Biopsy Needle has an 8 mm sample window and a 28 cm length.

5.2 Intended Use of the Device

The intended use of the Ad-Tech Brain Biopsy Needle is the same as predicate devices:

The Brain Biopsy Needles are used during guided procedures and methods deemed safe by the physician/surgeon to remove a targeted tissue sample for biopsy.

5.3 Summary of Technological Characteristics

The following table provides a side-by-side comparison the Ad-Tech Brain Biopsy Needle to the predicate devices being used to support this notification.

Table 5.3-1: Substantial Equivalence Technical Characteristics

Feature	Ad-Tech Brain Biopsy Needle Including MRI Conditional Variations (Under Review)	Ad-Tech Brain Biopsy Needle K924348	K990278 NeuroCut NeuroBiopsy Needle	K060808 BrainPro Cannula for Brain Biopsy
Indications for Use	The Brain Biopsy Needles are used during guided procedures and methods deemed safe by the physician/surgeon to remove a targeted tissue sample for biopsy.	The Brain Biopsy Needles are used during stereotactic guided procedures to remove a targeted tissue sample for biopsy	The Daum NeuroCut NeuroBiopsy Needle is designed for biopsy of the soft tissue in the brain. The patented surface treatment of the needle optimizes its use in the MRI setting, producing a low-artifact visualization of the needle.	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.
Single Patient Disposable	Yes	Yes	Yes	Yes
Sterile	Yes	Yes	Yes	Yes
MRI Compatible	Yes, Once variation: 8 mm Sample Window, 28 cm Length	No	Yes	Yes

5.4 Performance tests to demonstrate substantial equivalency:

To establish the MRI Compatibility of the Model MDBN-08-28 Brain Biopsy Needle variation, MRI modeling and MRI testing were performed to confirm acceptable performance under expected MRI conditions.

5.5 Conclusion

The MRI Compatibility of the Model MDBM-08-28 Brain Biopsy Needle variation demonstrated acceptable performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ad-Tech Medical Instruments Corp.
c/o Mr. Gary Syring
Principal Consultant
800 Levanger Lane
Stoughton, WI 53589

APR 2 4 2012

Re: K112094
Trade/Device Name: Brain Biopsy Needle
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW, FCG
Dated: April 16, 2012
Received: April 17, 2012

Dear Mr. Syring:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

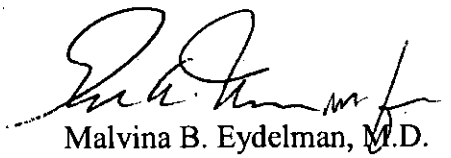
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112094

Indications for Use

510(k) Number (if known): K112094

Device Name: Brain Biopsy Needle

Indications for Use:

The Brain Biopsy Needles are used during guided procedures and by methods deemed safe by the physician/surgeon to remove a targeted tissue for biopsy.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112094