K032054

SEP 15 2003

Attachment VII: Summary of Safety and Effectiveness Information [510(k) Summary]

SUBMITTER:	Radionics, a division of Tyco Healthcare LP 22 Terry Ave. Burlington, MA 01803 Tel.: (781) 272-1233 Fax: (978) 663-8405 Contact: Kevin J. O'Connell Senior Regulatory Associate
PROPRIETARY NAME:	Radionics Nashold Biopsy Needle – Single Use (NBN-D)
COMMON OR USUAL NAME:	Disposable biopsy needle
CLASSIFICATION CODE:	21 C.F.R. § 882.4560
PREDICATE DEVICES:	MRI Devices Corporation (DAUM CORP.) Daum Neurocut Neurobiopsy Needle, K990278 Ad-Tech's Brain Biopsy Needle For Stereotaxic, K924348 Elekta Instrument's Leksell Sedan Biopsy Needle, 510(k) unk
INTENDED USE:	The Radionics Nashold Biopsy Needle is intended for single patient use in stereotactic biopsy of brain tumors.
DESCRIPTION:	The NBN-D is a dual cannula device made from stainless steel hypodermic needles. The device requires suction provided by a syringe to draw the tissue into the needle. The inner cannula is then rotated to cut the tissue. The device is designed to be used with the Radionics CRW system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 5 2003

Mr. Kevin J. O'Connell
Senior Regulatory Associate
Radionics
A Division of Tyco Healthcare LP
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K032054
Trade/Device Name: Radionics Nashold Biopsy Needle – Single Use
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: July 1, 2003
Received: July 2, 2003

Dear Mr. O'Connell:

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) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.0 ODE Indications Statement:

510(k) Number (if known): K032054

Device Name: Radionics Nashold Biopsy Needle – Single Use

The Radionics Nashold Biopsy Needle is intended for single patient use in stereotactic biopsy of brain tumors.

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

PRESCRIPTION USE ✓ OR Over-The-Counter Use ___

(Per 21 CFR 801.109

Miriam C. Provost (Optional Format 1-2-96)

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

510(k) Number K032054