

DEC - 9 1997

K974158

510(k) Summary

Orion Medical, Inc.
12187 South Business Park Drive, Suite 300
Draper, UT 84020

(801) 571-9774 Fax (801) 571-8840

Contact Name: Carol Freasier, Regulatory Affairs/QA

This submission was prepared on October 29, 1997.

Proprietary Name: Orion Medical Inc. Disposable Brain Biopsy Needle for stereotactic guided biopsy

Classification Name: 84 HAW, Disposable Brain Biopsy Needle

Common Name: Disposable Brain Biopsy Needle

Regulatory Class: Class II (882.4560)

Establishment Registration Number: 1723550

Intended Use:

The Orion Medical Disposable Brain Biopsy Needle is a fine aspiration biopsy needle to remove and sample tissue within the brain in conjunction with a stereotactic head frame. Indications include: (1) to sample brain tumor or to extract brain tissue samples to determine tissue abnormality or any deviation from healthy brain tissue; (2) The cannula is removed and the tissue sample is placed on a glass slide or sample dish, which is sent to anatomical pathology for smear analysis to determine tissue type; (3) to be used in conjunction with a stereotactic frame with a center-of-the-arc of 21cm. The needles are 21cm from the hub of the needle to the sharp front cutting edge.

Equivalent Devices:

Ad-Tech's Brain Biopsy Needle	(Ad-Tech Medical Instrument Corporation)	K924348
Field-Lee Brain Biopsy Needle	(V. Mueller)	K801760
NBN Brain Biopsy Needle	(Radionics, Inc.)	
BioTac Brain Biopsy Needle	(Progress Mankind Technology)	

Summary Statement:

The Orion Medical Inc. three piece disposable Brain Biopsy Needle for sampling brain tissue is to be used in conjunction with a stereotactic head frame. The Orion Medical disposable Brain Biopsy Needle is inserted in the brain through a burr hole via a stereotactic head frame to a desired target that is obtained by a CT image. Tissue samples are obtained by aspirating through the Orion Medical disposable Brain Biopsy Needle. The needle is then removed from the brain and the stereotactic system and the sample is expelled from the brain biopsy needle onto a dish or a slide for analysis. The Orion Medical disposable Brain Biopsy Needle is similar in geometry, safety, function, and intended use as currently available brain biopsy needles.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Orion Medical Incorporated
C/O Ms. Carol Freasier
Regulatory Affairs/Quality Assurance
Ortho Development Corporation
106 West 12200 South
Draper, Utah 84020

Re: K974158
Trade Name: Orion Medical Inc. Disposable Brain Biopsy Needle for Sterotactic
Guided Biopsy
Regulatory Class: II
Product Code: KNW
Dated: October 29, 1997
Received: November 3, 1997

Dear Ms. Freasier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

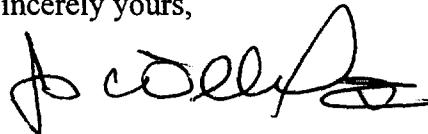
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for

devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

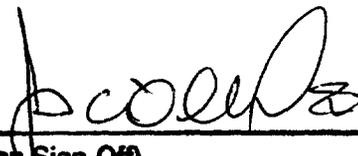
Premarket Notification for Disposable Brain Biopsy Needle

K974158

Indications for Use

The Orion Medical Disposable Brain Biopsy Needle is an aspiration biopsy needle to remove and sample tissue within the brain in conjunction with a stereotactic head frame. The following statement describes the indications for use of Orion Medical's 14 gauge, 16 gauge, and 18 gauge stereotactic disposable brain biopsy needle:

- Stereotactic biopsy needle used to sample brain tissue or to extract brain tissue samples to determine tissue abnormality or any deviation from healthy brain tissue.
- Tissue samples are extracted via the cannula using a syringe to aspirate. The cannula is then removed and the tissue sample is placed on a glass slide or sample dish, which is sent to anatomical pathology for smear analysis to determine tissue type.
- Needle to be used in conjunction with a stereotactic frame with a center-of-the-arc of 21cm. The needles are 21cm from the hub of the needle to the sharp front cutting edge.



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K974158

Prescription Use _____

(Per 21 CFR 801.109)

