K970578

Summary of Safety and Effectiveness

JUN - 4 1997

General Information

Classification:	Class II
Common Name:	Central nervous system fluid shunt component
Device Trade Name:	Radionics Burr Hole Valve
Intended Uses:	The Burr Hole Valve is designed to shunt cerebrospinal fluid from the ventricles of the brain to an appropriate drainage site, such as the atrium of the heart or the peritoneal cavity. It is designed to fit into a formal burr hole.
Predicate Device:	Radionics Contour Flex Valve and PS Medical Burr Hole Valve
Establishment Name and Address:	Radionics, Inc. 22 Terry Avenue Burlington, MA 01803
Contact Name and Phone:	Linda Jalbert, (617) 272-1233
Establishment registration number:	1219140
Performance Standard:	None established under Section 514

Substantial Equivalence Determination

A summary of the information contained in this premarket notification that addresses safety and effectiveness follows.

Safety Summary

The labeling for the Radionics Burr Hole contains instructions for the proper use of this device. The labeling includes a description of the product, directions for use, and applicable safety information including contraindications, precautions, and warnings. These instructions promote safe and effective use of the device, when followed by the physician.

Description of the Device and Basis for Substantial Equivalence

The Burr Hole Valve is designed for use as a cerebrospinal fluid shunt. It is the commercially available Radionics Contour Flex membrane valve with an alternate shaped reservoir/ pumping chamber; the Burr Hole Valve is shaped to fit into a burr hole. The Radionics Burr Hole Valve has the same intended use and design characteristics as the PS Medical Burr Hole Valve and the Radionics Contour Flex Valve. The Radionics Burr Hole Valve has the same reservoir shape and similar dimensions to the PS Medical Burr Hole Valve. Both of these valves are designed in two sizes to fit a 12 mm and 16 mm burr hole. The fluid flow path is the same for the Radionics Burr Hole Valve and the Contour Flex Valve. In addition, the flow control element is the same for the Burr Hole and Contour Flex Valves. The same polypropylene base/ silicone membrane valve component is used in both systems resulting in the same pressure flow specifications for each type of valve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 1997

Ms. Linda Jalbert
Manager, Regulatory Affairs
Radionics Instruments, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803-2516

Re: K970578
Trade Name: Radionics Burr Hole Valve
Regulatory Class: II
Product Code: 84JXG
Dated: May 12, 1997
Received: May 13, 1997

Dear Ms. Jalbert:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K970578

Device Name: Burr Hole Valve

Indications For Use:

Indications for Use

The Radionics Burr Hole Valve is indicated for the treatment of hydrocephalus. It is a device designed to shunt cerebrospinal fluid from the ventricles of the brain to an appropriate drainage site, such as the atrium of the heart or the peritoneal cavity. The Burr Hole Valve is designed to fit into a formal burr hole.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970578

Prescription Use X
(Per 21 CFR 801.109)

~~OR~~ ~~Over-The-Counter Use~~

(Optional Format 1-2-96)