K971511

JUL 24 1997

Summary of Safety and Effectiveness

General Information

Classification:	Class II
Common Name:	Central nervous system fluid shunt component
Device Trade Name:	Radionics Contour Flex Valve and Contour Flex Plus Valve
Intended Uses:	The Contour Flex Plus 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.
Predicate Device:	Radionics Contour Flex Valve and Contour Flex Plus 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 Contour Flex Valve and Contour Flex Plus contains instructions for the proper use of the device. The labeling includes a description of the product, directions for use, and applicable safety information including contraindications, precautions, and warnings. These instructions ensure safe and effective use of the device when followed by the physician.

Description of the Device and Basis for Substantial Equivalence

The Contour Flex Valve and Contour Flex Plus Valve are designed for use as a cerebrospinal fluid shunts. The Contour Flex Plus Valve is the Contour Flex membrane valve with an integral Siphon Limiting Device. The Siphon Limiting Device limits the reduction of the intraventricular pressure and volume caused by the siphoning effect caused by elevation of the ventricular catheter in relation to the distal catheter (often caused by the patient sitting or standing). This 510(k) covers the use of an alternate material for the upper housing of these valves. This material was subjected to and passes biocompatability testing like the unmodified commercially available valves, designed to meet the requirements of the ISO Standard 10993. In addition, performance testing was performed on the valves with the alternate material to confirm valve performance. There is no change to the design, dimensions, or specifications of the valves with the use of the alternate material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 24 1997

Re: K971511
Trade Name: Radionics Contour Flex Valve and Contour Flex Plus Valve
Regulatory Class: II
Product Code: 84JXG
Dated: April 25, 1997
Received: April 28, 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): K971511

Device Name: Radionics Contour Flex Valve and Contour Flex Plus Valve

Indications For Use:

The Contour Flex and Contour Flex Plus Valves are indicated for the treatment of hydrocephalus. They are devices 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 Contour Flex Plus Valve is indicated for patients where excessive reduction of intraventricular pressure or volume may be caused by the siphoning effect of hydrostatic pressure in the distal catheter of the shunt system.

(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 K971511

Prescription Use X **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)