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K964386

Summary of Safety and Effectiveness

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General Information

Classification:	Class II
Common Name:	Central nervous system fluid shunt component
Device Trade Name:	Radionics 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. It also prevents over-drainage of CSF due to siphoning.
Predicate Device:	Radionics Contour Flex Valve and PS Medical Delta CSF Flow Control Valve
Establishment Name and Address:	Radionics, Inc. 22 Terry Avenue Burlington, MA 01803
Contact Name and Phone:	Michael Arnold, Ph.D. (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 Plus 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 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 Plus Valve is designed for use as a cerebrospinal fluid shunt. It is the commercially available 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). The Radionics Contour Flex Plus Valve is a single unit which combines the features of the Contour Flex Valve and Siphon Limiting Device into a single, smaller unit for the surgeon's convenience. The Contour Flex Plus Valve has the same intended use and design characteristics as the PS Medical Delta CSF Flow Control Valve. Its valve component is the same as the Radionics Contour Flex Valve. Both the Radionics Contour Flex Plus Valve and the PS Medical Delta CSF Flow Control Valve have a siphon limiting device with an outlet port and a flexible diaphragm which opens or closes as the result of a change in hydrostatic pressure.