

K962990

OCT 23 1996

# Summary of Safety and Effectiveness

## General Information

Classification:	Class II
Common Name:	Central nervous system fluid shunt component
Device Trade Name:	Radionics Siphon Limiting Device (SLD)
Intended Uses:	As a component of a cerebrospinal fluid shunt system, the SLD prevents over-drainage of CSF due to siphoning.
Predicate Device:	PS Medical Siphon Control Device
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 SLD contains instructions for the proper use of this device. The labeling includes a description of the product, directions for use, and applicable safety information. 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 SLD is a device that limits the siphoning effect caused by elevation of the ventricular catheter in relation to the distal catheter. It has the same intended use and design characteristics as the PS Medical Siphon Control Device (SCD). Both the Radionics SLD and the PS Medical SCD have an inlet and outlet port, as well as a flexible diaphragm which opens or closes as the result of a change in hydrostatic pressure.