APR 7 2000

Exhibit I

510(k) Summary
SiphonGuard™ CSF Control Device

K992173

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

1. ***Contact Person:***

Laura O'Grady
Regulatory Affairs Specialist
(508) 828-3164

2. ***Device Information:***

Proprietary Name:	SiphonGuard™ CSF Control Device
Common Name:	Antisiphon Device
Classification Name:	Central Nervous system Fluid Shunt and Components
Regulatory Class:	Class II by 21 CFR §882.5550
Product Code:	JXG

3. ***Indications for Use:***

The SiphonGuard™ CSF Control Device is a component of hydrocephalus shunt systems designed to shunt CSF from the lateral ventricles of the brain into the peritoneal cavity or right atrium of the heart.

The SiphonGuard™ CSF Control Device is designed to reduce the potential hazards of excessive lowering of intraventricular pressure (with respect to atmospheric pressure) when a patient is in an upright position.

4. ***Device Description:***

The SiphonGuard™ CSF Control Device is a siphon control device that is designed with two internal passages. The primary passage is a ruby ball-in-seat valve design that opens and closes depending on the CSF flow rate. The secondary passage is a longer spiral passage that remains permanently open but effectively slows the progress of the CSF through the device. The device has two basic modes of operation:

Normal CSF Flow Conditions: Majority of the CSF flows through the ruby ball-in-seat valve and exits directly out of the distal port of the SiphonGuard™ CSF Control Device. The remaining CSF travels through a spiral passage that surrounds the primary passage, and rejoins the fluid that passes through the primary passage, distal to the ball-in-seat valve.

Excessive CSF Flow Conditions: Ball-in-seat valve closes and the entire volume of CSF is forced through the longer spiral passage, effectively slowing the rate at which CSF is shunted from the brain. Once the CSF flow rate is reduced, the ruby ball separates from the valve seat, reopening the primary passage, and returning the SiphonGuard™ CSF Control Device to normal CSF flow conditions.

As long as CSF continues to be shunted from the ventricles, flow through the secondary passage never stops, regardless of patient position. The rigid device shell prevents inadvertent closure of the device by externally applied pressure.

5. ***Performance:***

Pressure-flow test results showed that the SiphonGuard™ CSF Control Device is substantially equivalent to the Delta® Valve antisiphon component and the Transguard™ antisiphon device in reducing CSF flow rate.

6. ***Substantial Equivalence:***

The substantial equivalence of the SiphonGuard™ CSF Control Device to predicate products, is substantiated by its similarity in intended use, design, and performance to the Delta® Valve (K902783), and Transguard™ device (pre-amendment), as well as by the use of the identical materials used in the CODMAN HAKIM™ Micro Precision Valve (K973774).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2000

Ms. Laura O'Grady, RAC
Regulatory Affairs Specialist
Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K992173
Trade Name: SiphonGuard™ CSF Control Device
Regulatory Class: II
Product Code: JXG
Dated: January 7, 2000
Received: January 10, 2000

Dear Ms. O'Grady:

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 requirement, 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

510(k) Number (if known) K992173

Device Name ***SiphonGuard™ CSF Control Device***

Indications For Use

The SiphonGuard™ device can be used as a component of hydrocephalus shunt systems designed to shunt CSF from the lateral ventricles of the brain into the peritoneal cavity or right atrium of the heart.

The SiphonGuard™ device is designed to reduce the potential hazards of excessive lowering of intraventricular pressure (with respect to atmospheric pressure) when a patient is in an upright position.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmen.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992173

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)