EXHIBIT I

K974739

JUL 1 1998

510K Summary
HP Valve System
December 18, 1997

1. Submitter

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767
Diane Minear, Senior Regulatory Consultant, (508) 828-3532

2. Device Name

Proprietary Name:	HP Valve System
Common Name:	Hydrocephalus Shunt
Classification Name:	Central Nervous System Fluid Shunt and Components
Regulatory Class:	Class II by 21 CFR §882.5550

3. Intended Use

The HP Valve System is an implantable device that provides constant intraventricular pressure and drainage of cerebrospinal fluid (CSF) for the management of hydrocephalus.

4. Device Description

The HP Valve System is a hydrocephalus shunt designed to allow the surgeon to change the valve operating pressure without surgical intervention. Intraventricular pressure is maintained at a constant level by the device's rubyball-in-cone valve seat design. The center of a flat spring is attached to a fixed fulcrum, with one end resting on the ruby ball and the other end resting on an eighteen position spiral staircase shaped cam that rotates on a titanium pivot. When the cam rotates the tension on the spring changes as the distal end of the spring moves up or down the cam. The operating pressure of the valve is thereby adjusted. During programming, the programmer transmits a coded magnetic signal to the device, causing the cam to rotate. The device has 18 pressure settings, ranging from 30mm to 200mm H20, in 10mm increments.

5. Predicate Device Comparison

The HP Valve System is substantially equivalent in terms of intended use, materials, design, manufacturing, and function to the HAKIM Precision Valve System (K944222). Both devices utilize the same ball-in-cone valve mechanism to maintain intraventricular pressure. The valve design maintains intraventricular pressure at a constant selected level. Depending on the CSF flow rate and/or viscosity, the ball moves up or down within the cone under the control of the calibrated flat stainless steel spring. The cross section of the valve through which CSF flows automatically increases or decreases, therefore maintaining the selected pressure.

While the pressure regulating mechanism is identical in both devices, the variable pressure setting feature is only available with the HP Valve System, while the HAKIM Precision Valve System is available in five fixed pressure ranges.

6. Device Testing Summary

Testing Performed	Comments
Biocompatibility Testing	Biocompatibility tests were performed per the *Tripartite Biocompatibility Guidance for Medical Devices* and *ISO 10993 Biological Testing of Medical and Dental Materials and Devices.* Testing results demonstrated that the device materials are biocompatible.
Performance Testing	Performance testing was conducted per and complies with the applicable sections of *ASTM F647-94 - Standard Practice for Evaluating and Specifying Impantable Shunt Assemblies for Neurosurgical Applications.* Performance testing included the following areas; Reprogramming, Fatigue, Corrosion, MRI, Wet Pressure and Programmer Evaluation. Testing results demonstrated the suitability of the device for its intended use.
Clinical Evaluation	A controlled, randomized, clinical trial was conducted to support a claim of substantial equivalence. 377 patients were enrolled and followed for two years. Results indicated that the HP Valve System performs as well as and is as safe and effective as currently marketed hydrocephalus shunt systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 1998

Ms. Diane Minear
Senior Regulatory Consultant
Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K974739
Trade Name: Hakim Programmable Valve System
Regulatory Class: II
Product Code: JXG
Dated: June 24, 1998
Received: June 25, 1998

Dear Ms. Minear:

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

HAKIM PROGRAMMABLE VALVE SYSTEM
INDICATIONS FOR USE

K974739

The HP Valve System is an implantable device that provides constant intraventricular pressure and drainage of cerebrospinal fluid (CSF) for the management of hydrocephalus.

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974739

Prescription Use X
(Per 21 CFR §801.109)

OR

Over-the-Counter Use_____

(Optional Format 1-2-96)