K973774

DEC 29 1997

510(k) Summary
CODMAN HAKIM™ Micro Precision Valve

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

1. **Contact Person:**

Janet G. Johnson, Assoc. Regulatory Affairs Specialist, (508) 828-3466

2. **Device Name:**

Proprietary Name:	CODMAN HAKIM™ Micro Precision Valve
Common Name:	Hydrocephalus Shunt
Classification Name:	Central Nervous System Fluid Shunt and Components
Regulatory Class:	• Class II by 21 CFR §882.5550
Product Code:	• 84 JXG
Owner/ Operator #	9001269

3. **Device Classification:**

Classification for CODMAN HAKIM™ Micro Precision Valve has been placed in Class II by 21 CFR §882.5550.

4. **Statement of Substantial Equivalence:**

The safety and effectiveness of the CODMAN HAKIM™ Micro Precision Valve is substantially equivalent in terms of intended use, materials, design, manufacturing and function to the Codman-Medos Shunt Valve System (K944222).

5. **Indications for Use:**

The CODMAN HAKIM™ Micro Precision Valve System is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus and other conditions in which CSF flow and absorption are impaired.

6. **Physical Description:**

The CODMAN HAKIM™ Micro Precision Valve incorporates a flat 316L stainless steel spring. Intraventricular pressure is maintained at a constant level by the synthetic ruby ball-in-cone valve seat design. Depending on the cerebrospinal (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.

The silicone rubber housing of the CODMAN HAKIM™ Micro Precision Valve has a flat bottom to better stabilize the position of the valve underneath the scalp. The flat underside of the valve should be placed against the bone.

The operating pressures of the valve are set and verified at the time of manufacture. The valve is classified by the operating pressure, not by the opening and closing pressures. The total pressure of the valve is controlled by the inlet valve. The CODMAN HAKIM™ Micro Precision Valve is available in five pressure settings:

Very Low	10 ± 10 mm H_2O
Low	40 ± 10 mm H_2O
Medium	70 ± 10 mm H_2O
Medium High	100 ± 10 mm H_2O
High	130 ± 10 mm H_2O

The materials of the CODMAN HAKIM™ Micro Precision Valve are the same materials that are used in the currently marketed Codman-Medos Shunt Valve System (K944222). The only difference in materials is in the accessories. The stainless steel connector described in K944555 has been replaced with a nylon connector that was cleared in the Accu-Flo Pressure Valve submission (K853215A).

Similarities and Differences Matrix

	CODMAN HAKIM™ Micro Precision Valve	Codman-Medos Shunt Valve System (K944222)
DESIGN:		
Ball-in-cone:	Yes	Yes
Inlet Spring:	Flat	Flat
Operating Pressures: 10 ± 10 mm H_2O (Very Low) 40 ± 10 mm H_2O (Low) 70 ± 10 mm H_2O (Medium) 100 ± 10 mm H_2O (Medium High) 130 ± 10 mm H_2O (High)	Yes	Yes
Pressure Determinant	Inlet Valve	Inlet Valve
Pressure Identification	Dot Code	Color Code
Housing Bottom	Flat	Blended to Round
Pumping Chamber	No	Yes
Outlet	No	Yes
Inlet Valve	Yes	Yes
Anti-Reflux Mechanism	Inlet Valve	Outlet
Priming Adapter	Yes	No
Pre-chamber	With and Without	With and Without

	CODMAN HAKIM™ Micro Precision Valve	Codman-Medos Shunt Valve System (K944222)
AVAILABILITY:		
Valve System	Yes	Yes
Valve unit alone	Yes	Yes
System components alone	Yes	Yes
INTENDED USE:		
The CODMAN HAKIM™ Micro Precision Valve System is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus and other conditions in which CSF flow and absorption are impaired.	Yes	Yes
PACKAGING:		
Double Peel Blister Tray	Yes	Yes
STERILIZATION:	EtO	EtO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1997

Ms. Janet G. Johnson
Associate Regulatory Affairs Specialist
Johnson & Johnson Professionals, Incorporated
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K973774
Trade Name: Codman Hakim Micro Precision Value
Regulatory Class: II
Product Code: JXG
Dated: October 2, 1997
Received: October 3, 1997

Dear Ms. Johnson:

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 requirements , 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

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Indications For Use
for the CODMAN HAKIM™ Micro Precision Valve System

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Indications for Use

The CODMAN HAKIM™ Micro Precision Valve System is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus and other conditions in which CSF flow and absorption are impaired.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973774

Prescription Use ✓
(Per 21 CFR 801.109)