K964923

Summary of Safety and Effectiveness Data for the Lumbar Drainage Catheter Kit

JUN 2 5 1997

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

Contact Person

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Name of Device

Proprietary Name:	CODMAN Lumbar Drainage Catheter Kit
Common Name:	Lumbar Drainage Catheter Kit
Classification Name:	Central nervous system fluid shunt and components
Regulatory Class:	Class II by 21 CFR §882.5550
Product Code No.:	84JXG
Owner/Operator No.:	9001269

Device Classification

This device has been placed in Class II for Central nervous system fluid shunt and components per 21 CFR § 882.5550.

Statement of Substantial Equivalence

The Lumbar Drainage Catheter Kit is substantially equivalent to the Cordis Lumbar Catheter Accessory Kit currently marketed in the United States under #K855058.

The subject device is composed of similiar materials to the Cordis Lumbar Catheter Accessory Kit. Further, the intended use, design, and manufacture of the Lumbar Drainage Catheter Kit are substantially equivalent to the currently distributed. Additionally, the packaging and method of sterilization utilized for the Lumbar Drainage Catheter Kit are the same as those used for the Lumbar Catheter Accessory Kit

Indications for Use

The Lumbar Drainage Catheter Kit has the same indications for use as the Cordis Lumbar Catheter Accessory Kit. They are both indicated for use in conjunction with other devices to drain cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing increased intracranial volume and pressure.

Physical Description

The Lumbar Drainage Catheter Kit consists of an 80cm lumbar catheter having an inner diameter of .76mm. The catheter has 13 tantalum location markings to assist the surgeon. The initial mark is located at 11.4 cm with a mark every 1cm thereafter for 10cm, and additional marks at 15cm and 20cm. Also included are a cm-marked 14 gauge thin wall Touhy needle with optional stabilizing wings; a 100 cm Teflon coated, flexible tip guidewire with an outer diameter of 0.5mm; a plastic female Luer-Lok connector, with barbed end and plastic Luer-Lok cap, that is installed on the distal end of the catheter in preparation for connection to monitoring equipment or fluid collection equipment; and a soft suture tab for holding the catheter in position.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James M. Flaherty, Jr.
Associate Regulatory Affairs Specialist
Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

JUN 25 1997

Re: K964923
Trade Name: CODMAN® Lumbar Drainage Catheter Kit
Regulatory Class: II
Product Code: 84JXG
Dated: March 31, 1997
Received: April 3, 1997

Dear Mr. Flaherty:

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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Indications for Use
Lumbar Drainage Catheter Kit

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

Indications for Use

The Lumbar Drainage Catheter Kit is indicated for temporary access to the lumbar subarachnoid region and, when used with other Codman devices, is designed to drain cerebrospinal fluid (CSF) as a means of reducing increased intracranial volume and pressure.

Prescription Use
(Per 21 CFR 801.109)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964923