JUL - 9 1999

K991222

510(k) Summary
for the CODMAN® MICROSENSOR™ Ventricular Catheter Kit

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

Contact Person

James M. Flaherty, Jr., RAC
Regulatory Affairs Specialist
Telephone Number: (508) 880-8404
Fax Number: (508) 828-3212

Name of Device

Proprietary Name:	CODMAN® MICROSENSOR™ Ventricular Catheter Kit
Common Name:	Intracranial pressure (ICP) monitoring/cerebrospinal fluid (CSF) drainage catheter kit
Classification Name:	• Intracranial pressure monitoring device • Ventricular catheter

Device Classification

This device has been placed in Class II for intracranial pressure monitoring devices per 21 CFR § 882.1620 (84GWM) as well as for ventricular catheters per 21 CFR § 882.4100 (84HCA).

Statement of Substantial Equivalence

The CODMAN® MICROSENSOR™ Ventricular Catheter Kit is substantially equivalent to both the CODMAN® MICROSENSOR™ Catheter Kit and the CAMINO NeuroCare™, Inc. Ventrix™ Ventricular Tunneling Pressure Monitoring Kit based on the subject device's similarity to the predicate devices in intended use, materials, design, and principles of operation.

Indications for Use

Use of the CODMAN® MICROSENSOR™ Ventricular Catheter Kit is indicated when direct intracranial pressure (ICP) monitoring is required. The kit is indicated for use in intraventricular pressure monitoring and cerebrospinal fluid (CSF) drainage applications.

Physical Description

The CODMAN® MICROSENSOR™ Ventricular Catheter Kit consists of the following components:

(1) Ventricular Catheter – Triple-lumen catheter with a center drainage lumen and dedicated lumens for the stylet and MICROSENSOR™ ICP Sensor,
(2) Stylet – Preloaded stylet sued for catheter insertion and placement,
(3) MICROSENSOR™ ICP Sensor – Intracranial pressure (ICP) sensor embedded in a dedicated lumen with direct CSF access,
(4) Y-Connector – Connection component allowing the catheter to be either connected to an external drainage system or capped,
(5) Suture Clip – Catheter anchoring clip, and
(6) Tunneling Trocar with TEFLON® Tubing – Trocar with sheath designed to allow the catheter to be tunneled under the scalp to the craniotomy site.

Device Testing

This submission relied on appropriate testing in accordance with ISO 10993-1 "Biological Testing of Medical and Dental Materials and Devices, Part 1: Guidance on Selection of Tests" and the "Tripartite Biocompatibility Guidelines for Medical Devices" as well as material characteristics of the silicone elastomer as furnished by the material supplier. All testing supports the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL -9 1999

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

Re: K991222
Trade Name: Codman Microsensor Ventricular Catheter Kit
Regulatory Class: II
Product Code: GWM
Dated: April 9, 1999
Received: April 12, 1999

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) 594-4595. 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) K991222

Device Name **CODMAN® MICROSENSOR™ Ventricular Catheter Kit**

Indications For Use:

Use of the CODMAN® MICROSENSOR™ Ventricular Catheter Kit is indicated when direct intracranial pressure (ICP) monitoring is required. The kit is indicated for use in intraventricular pressure monitoring and cerebrospinal fluid (CSF) drainage applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices K991222