K974088

JAN - 9 1998

510(k) Summary
for the CODMAN® Intracranial Bolt

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

Contact Person

James M. Flaherty, Jr.
Associate Regulatory Affairs Specialist
Telephone Number: (508) 880-8404
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Name of Device

Proprietary Name: CODMAN® Intracranial Bolt
Common Name: Intracranial Bolt
Classification Name: Intracranial pressure monitoring device

Device Classification

This device has been placed in Class II for intracranial pressure monitoring devices per 21 CFR § 882.1620 (84GWM).

Statement of Substantial Equivalence

The CODMAN® Intracranial Bolt is substantially equivalent to both the CODMAN® MicroSensor™ Skull Bolt and Camino ICP Bolt based on the subject device's similarity to the predicate devices in intended use, materials, design, and principles of operation.

Indications for Use

The CODMAN® Intracranial Bolt is indicated for use as a component of an intracranial pressure (ICP) monitoring system designed to achieve direct ICP monitoring. Specifically, the CODMAN® Intracranial Bolt is intended to secure an ICP transducer during direct ICP monitoring in both subdural and intraparenchymal applications.

Physical Description

The CODMAN® Intracranial Bolt is composed of the following six components: (1) bolt, (2) wing nut, (3) compression cap, (4) compression grommet, (5) washer, and (6) obturator/dura pierce (packaged with bolt assembly). The bolt component is screwed into the cranium in order to secure the transducer. This is achieved through compression of the grommet via tightening of the compression cap. Additionally, a wing nut is provided as a component of the assembly as a means of bolt insertion, and a washer is provided if thread depth variation is desired. Finally, an obturator/dura pierce is provided to clear the inner lumen of the bolt and pierce the dura prior to transducer insertion. All patient contacting components are constructed of fully biocompatible implant materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K974088
Trade Name: Codman Intracranial Bolt
Regulatory Class: II
Product Code: GWM
Dated: October 29, 1997
Received: October 30, 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.

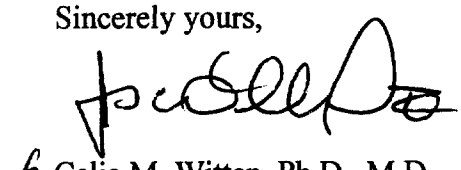
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice 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,



for 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) K974088

Device Name **CODMAN® Intracranial Bolt**

Indications For Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974088

Prescription Use X
(Per 21 CFR §801.109)

OR

Over-the-Counter Use_____

(Optional Format 1-2-96)