

OCT 15 1999

K992591

**510(k) Summary
for the CODMAN® Single and Double Lumen Skull Bolt Kits**

**Codman & Shurtleff, 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® Single and Double Lumen Skull Bolt Kits
Common Name: Intracranial Bolts
Classification Name: Intracranial pressure monitoring devices

Device Classification _____

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

Statement of Substantial Equivalence _____

The CODMAN® Single and Double Lumen Skull Bolt Kits are substantially equivalent to both the CODMAN® MICROSENSOR™ Skull Bolt Kit and the CAMINO Micro Ventricular Bolt 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 _____

The CODMAN® Single Lumen Skull Bolt Kit is designed to achieve cranial access and to introduce and secure a sensor in place for intracranial monitoring applications.

The CODMAN® Double Lumen Skull Bolt Kit is designed to achieve cranial access and to introduce and secure sensors in place for intracranial monitoring applications.

Physical Description

The CODMAN® Single and Double Lumen Skull Bolt Kits consist of bolts and associated components designed to achieve cranial access and facilitate the introduction and securing of intracranial sensors. Additional accessories supplied in the kits include a sensor introducer, connectors, drill bits, and other associated components supplied for the convenience of the user. All parts and accessories found in the CODMAN® Single and Double Lumen Skull Bolt Kits are manufactured from biocompatible materials suitable for their uses in these kits.

Device Testing

This submission relied on bench testing to demonstrate equivalence of performance characteristics to predicate products. Torque, pullout, and leak testing of both the single and double lumen bolts demonstrated that the devices are appropriate for their intended use.



OCT 15 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James Flaherty, Jr., RAC
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K992591
Trade Name: Codman Single and Double Lumen Skull Bolt Kits
Regulatory Class: II
Product Code: GWM
Dated: July 30, 1999
Received: August 2, 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 enclosures) 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.

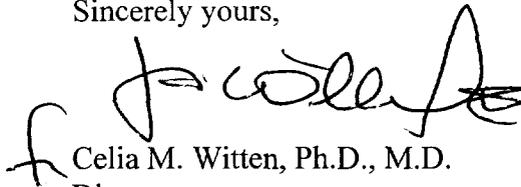
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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) K 992591
Device Name CODMAN® Single and Double Lumen
Skull Bolt Kits

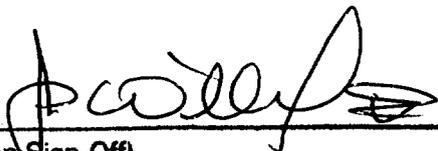
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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992591

Prescription Use
(Per 21 CFR §801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)