

AUG 1 2000

K992905

**510(k) Summary
for the CODMAN® CRANIOSORB™ Absorbable Fixation System**

**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® CRANIOSORB™ Absorbable Fixation System
Common Name: Craniofacial absorbable fixation system
Classification Name: Cranioplasty plates, plate fasteners, and burr hole covers

Device Classification _____

These devices have been placed in Class II for preformed alterable cranioplasty plates per 21 CFR § 882.5320 (84GWO), for cranioplasty plate fasteners per 21 CFR § 882.5360 (84HBW), and for burr hole covers per 21 CFR § 888.5250 (84GXR).

Statement of Substantial Equivalence _____

The CODMAN® CRANIOSORB™ Absorbable Fixation System is substantially equivalent to both the LactoSorb® Trauma Plating System (K971870) and the MacroPore Protective Sheet (K972913) 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® CRANIOSORB™ Absorbable Fixation System is intended for surgical procedures in which internal fixation is required to align and stabilize bony tissue for craniofacial skeletal reconstruction and the repair of traumatic fractures of the craniofacial skeleton.

Physical Description

The CODMAN® CRANIOSORB™ Absorbable Fixation System consists of plates, mesh, and rivets to be used in craniofacial reconstruction. The 1mm thick absorbable plates and mesh are designed in various shapes and sizes typical of other marketed fixation devices. The biocompatible implant material used to manufacture the plates and mesh is a blend of poly(D,L-Lactide), polycaprolactone, and polydioxanone. The rivets are constructed of poly L-lactic acid (PLLA).

Device Testing

Five (5) different performance tests were conducted on the CODMAN® CRANIOSORB™ Absorbable Fixation System in order to assess device suitability for its intended use. These studies evaluated retained strength over time, dimensional stability, simulated bend testing and pullout/push out testing. In addition, biocompatibility testing was performed on the polymer blend used to manufacture the CRANIOSORB™ Plates and Mesh including cytotoxicity, genotoxicity, sensitization, and implant studies of tissue reaction



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 1 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K992905
Trade Name: Codman Craniosorb Absorbable Fixation System
Regulatory Class: II
Product Code: JEY
Dated: May 2, 2000
Received: May 3, 2000

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 legally marketed predicate 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.

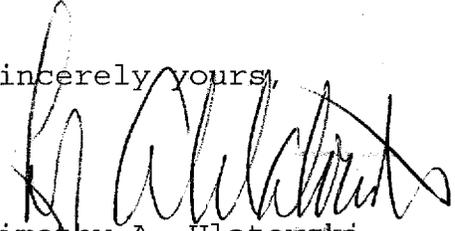
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Flaherty

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) 594-4692. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known)

Device Name

**CODMAN® CRANIOSORB™
Absorbable Fixation System**

Indications For Use:

The CODMAN® CRANIOSORB™ Absorbable Fixation System is intended for surgical procedures in which internal fixation is required to align and stabilize bony tissue for craniofacial skeletal reconstruction and the repair of traumatic fractures of the craniofacial skeleton.

The CODMAN® CRANIOSORB™ Absorbable Fixation System is contraindicated for use in the mandible and as a primary source of fixation in weight bearing areas.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992405

Prescription Use
(Per 21 CFR §801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)