MAR 1 3 2000

510K Summary
CODMAN ETHISORB™ Dura Patch
March 8, 2000

K991413

1. Submitter

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767
Deana Boushell, Manager Regulatory Affairs, (508) 828-3107

2. Device Name

Proprietary Name:	CODMAN ETHISORB™ Dura Patch
Common Name:	Dura Substitute
Classification Name:	Dura Substitute
Regulatory Class:	Class II by 21 CFR §882.5910

3. Intended Use

The CODMAN ETHISORB™ Dura Patch is a synthetic, absorbable implant intended for bridging defects of the dura mater.

4. Device Description

The CODMAN ETHISORB™ Dura Patch is composed of a composite fleece fabric of polyglactin 910 and polydioxanone yarns, with a polydioxanone film dyed with D&C Violet No. 2 on one surface. The porous structure of the fleece allows tissue on-growth while the PDS film coating minimizes leakage of cerebrospinal fluid (CSF). The device is provided sterile and ready for implantation in a foil pouch. Animal and clinical trials have demonstrated that the device is suitable for its intended use. The implant material is fully biocompatible and absorbable over time

5. Predicate Device Comparison

The CODMAN ETHISORB™ Dura Patch is similar to other dura substitutes with respect to its design as a thin, flexible, impermeable sheet of material which is both biocompatible and sufficiently strong enough to bridge the dural defect until healing occurs. Examples of predicate products with these same characteristics include the Dura-Guard™ Dural Repair Patch by Bio-Vascular, Inc., (K950956) and the Neuro-Patch by Aesculap®, Inc. (K960470). The Dura Patch differs from the predicate devices only in that once it has fulfilled its function and is no longer needed to cover the defect, it is hydrolyzed and absorbed slowly over time.

6. Device Testing Summary

Testing Performed	Comments
Biocompatibility Testing	Although all materials used in the device have been shown to be bicompatible implant materials, additionaltests were performed on final Dura Patch product, including pyrogenicity, cytocoxicity, and implant studies of tissue reaction.
Performance Testing	Performance testing was conducted in the target tissue to confirm device suitability for its intended use as a dura substitute.
Clinical Evaluation	A prospective non-randomized clinical trial was conducted to demonstrate the clinical performance characteristics of the device. Results of all testing demonstrate that the ETHISORB™ Dura Patch is equivalent to currently marketed products in its performance as a safe and effective dura substitute.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2000

Ms. Deana Boushell, RAC
Team Leader, Regulatory Affairs
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K991413
Trade Name: ETHISORB™ Dura Patch
Regulatory Class: II
Product Code: GXQ
Dated: January 10, 2000
Received: January 11, 2000

Dear Ms. Boushell:

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,

Neil R. P. Ogden for

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

Device Name: **CODMAN ETHISORB™ Dura Patch** K 99 1413

The CODMAN ETHISORB™ Dura Patch is an absorbable, synthetic implant for bridging defects of the dura mater.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

MRD for JZD

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K991413

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR §801.109)

(Optional Format 1-2-96)