510(k) Summary

SEP - 8 2003

Submitted By: Mark Bleyer, President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355
June 13, 2003

Names of Device:

Trade Name:	Durasis® Dural Substitute
Common/Usual Name:	Dural substitute, dural graft, dural repair patch
Classification Name:	Dura Substitute 21 CFR § 882.5910 (84GXQ)

Intended Use:
Durasis® Dural Substitute is intended for use as a dura substitute for repairing dura mater. The device is intended for one-time use.

Predicate Devices:
Predicate devices are Dura-Guard® Dural Repair Patch (K950956), manufactured by Bio-Vascular, Inc., Tutoplast® Processed Dura Mater (K910555), marketed by Biodynamics International, Inc., CODMAN ETHISORB™ Dura Patch (K991413), marketed by Johnson & Johnson, Surgisis® Soft Tissue Graft (K980431), manufactured by Cook Biotech Incorporated, and DuraGen Dural Matrix (K982180) manufactured by Integra Neurosciences.

Device Description:
Durasis® Dural Substitute is manufactured from porcine small intestinal submucosa and is supplied in various sizes ranging up to 140 cm^2. The device is packaged in sterile, sealed double pouches.

Substantial Equivalence:
Durasis® Dural Substitute is comparable with respect to intended use, materials of composition, and technical characteristics to predicate devices in terms of 510(k) substantial equivalence.

Discussion of Tests and Test Results:
The material comprising Durasis® Dural Substitute was subjected to *in vitro*, *in vivo*, and clinical evaluation to assess biocompatibility, mechanical properties, performance characteristics, and safety. The material met the criteria, providing reasonable assurance of device performance for its intended use and supporting substantial equivalence.

Conclusions Drawn from Tests:
Outcomes from the evaluation of Durasis® Dural Substitute provide evidence of its suitability for dura mater replacement and of substantial equivalency to predicate devices in terms of intended use and technological characterstics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2003

Mr. Mark Bleyer
President
Cook Biotech, Inc.
3055 Kent Avenue
West Lafayette, Indiana 47906

Re: K031850
Trade/Device Name: Durasis® Dural Substitute
Regulation Number: 21 CFR 882.5910
Regulation Name: dura substitute
Regulatory Class: II
Product Code: GXQ
Dated: June 13, 2003
Received: June 19, 2003

Dear Mr. Bleyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K031850

510(k) Number (if known): K031850

Device Name: **Durasis® Dural Substitute**

Indications For Use:

Durasis® Dural Substitute is intended for use as a dura substitute for repairing dura mater. The device is provided sterile and intended for one-time use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031850

Prescription Use_____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)