K980431

MAY 28 1998

I. 510(K) SUMMARY

Submitted By: Neal E. Fearnot, Ph.D.
President
Cook Biotech, Incorporated
P.O. Box 2402
West Lafayette, IN 47906
(765) 497-3355
February 2, 1998

Names of Device:

Trade Name:	Surgi*SIS*™
Common/Usual Name:	Surgical Mesh, Soft Tissue Patch
Proposed Classification Name:	Surgical Mesh (21 CFR §878.3300)

Predicate Devices:
Supple Peri-Guard® Pericardium (K961810) manufactured by Bio-Vascular, Inc.
GraftPatch® Soft Tissue Surgical Patch (K970561) manufactured by Organogenesis, Inc.
DEXON Polyglycolic Acid Mesh (K830889) manufactured by Davis & Geck, Inc.

Device Description:
Surgi*SIS*™ is supplied in sheet form in sizes ranging from 16 cm^2 to 360 cm^2. The device is packaged in sterile sealed pouches.

Intended Use:
Surgi*SIS*™ is intended to be used for implantation to reinforce soft tissue. It is intended for one-time use.

Substantial Equivalence:
Surgi*SIS*™ is substantially equivalent to the predicate devices, having similar intended use and technological characteristics.

Discussion of Tests and Test Results:
The Surgi*SIS*™ material was subjected to a panel of tests to assess biocompatibility, integrity, and performance. Surgi*SIS*™ passed the requirements of all tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1998

Neal E. Fearnot, Ph.D.
President
Cook Biotech Incorporated
P.O. Box 2603
3055 Kent Avenue
West Lafayette, Indiana 47906

Re: K980431
Trade Name: SurgiSIS™ Surgical Mesh
Regulatory Class: II
Product Code: FTM
Dated: April 30, 1998
Received: May 5, 1998

Dear Dr. Fearnot:

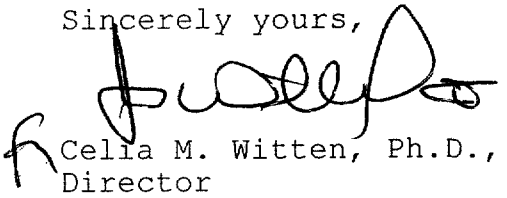
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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): K980431

Device Name: Surgi*SIS*™

Indications For Use:

Surgi*SIS*™ is intended for implantation to reinforce soft tissue. This device is 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980431

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)