MAR 9 - 2005

K050337

1/1

9. 510(K) Summary

Submitted By: Mark Bleyer, President
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
(765) 497-3355
March 2, 2005

Names of Device:

Trade Name:	SIS Fistula Plug
Common/Usual Name:	Surgical Mesh
Proposed classification name:	Surgical Mesh 21 CFR 878.3300 (FTM) Class II

Intended Use:

The SIS Fistula Plug is for implantation to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal, and enterocutaneous fistulas. The device is supplied sterile and is intended for one-time use.

Predicate Devices:
The SIS Fistula Plug is similar to predicate devices, including the SURGISIS® Soft Tissue Graft (K980431) and the STRATASIS® Urethral Sling (K992159), both manufactured by Cook Biotech Incorporated.

Device Description:
The SIS Fistula Plug is manufactured from porcine small intestinal submucosa (SIS) and is nominally supplied in a rolled and tapered configuration. The device is packaged in a lyophilized (dried) state, and supplied sterile in a sealed double pouch system.

Substantial Equivalence:
The SIS Fistula Plug is similar with respect to intended use, materials and technological characteristics to the above predicate devices in terms of 510(k) substantial equivalence as shown through bench and biocompatibility testing and clinical experience.

Discussion of Tests and Test Results:
The material comprising the SIS Fistula Plug was subjected to extensive biocompatibility testing, viral inactivation testing, and mechanical testing. Outcomes show the device to be biocompatible, manufacturing processes to adequately disinfect the material, and mechanical characteristics to be sufficient.

Conclusions Drawn from the Tests:
Outcomes from the evaluation of the SIS Fistula Plug provide evidence of its suitability for use in soft tissue reconstruction and substantial equivalency to predicate devices in terms of intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 9 - 2005

Mr. Mark Bleyer
President
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K050337
Trade/Device Name: SIS Fistula Plug
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTM
Dated: February 9, 2005
Received: February 10, 2005

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K050337

Indications for Use

510(k) Number (if known): **K050337**
Device Name: **SIS Fistula Plug**
Indications for Use:

The SIS Fistula Plug is for implantation to reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal, and enterocutaneous fistulas. The device is supplied sterile and is intended for one-time use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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, and Neurological Devices

510(k) Number K050337