K073391

9 510(K) SUMMARY

Submitted by:

MAR 21 2008

Perry W. Guinn
VP Regulatory Affairs and Quality Assurance
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
(765) 497-3355
November 30, 2007

Device:

Trade Names:	SURGISIS® Biodesign Tissue Graft, SIS Hernia Repair Device
Common/Usual Name:	Surgical Mesh
Proposed Classification Name:	Surgical Mesh 21 CFR §878.3300 (79FTM) Class II

Intended Use:
The SURGISIS® Biodesign Tissue Graft is intended to be implanted to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect.
The SURGISIS® Biodesign Tissue Graft minimizes tissue attachment to the device in case of direct contact with viscera.

The device is intended for one-time use.

Predicate Devices:
The SURGISIS® Biodesign Tissue Graft is substantially equivalent to itself (D.C. #K062697) acting as its own predicate and is substantially equivalent to Veritas® Collagen Matrix (D.C. #K062915) manufactured by Synovis Surgical Innovations.

Device Description:
The SURGISIS® Biodesign Tissue Graft is manufactured from porcine small intestinal submucosa (SIS) and is nominally supplied in a range of sizes. The device is packaged in a dried state, and is supplied sterile in a sealed double pouch system.

Substantial Equivalence:
The SURGISIS® Biodesign Tissue Graft is similar with respect to intended use, materials and technological characteristics to its predicate devices in terms of section 510(k) substantial equivalence, as shown through bench and biocompatibility testing submitted in previous cleared 510(k)s.

Indication Testing:
A number of animal studies from published and unpublished literature were conducted specific to the subject of this submission. All studies concluded that SURGISIS® Biodesign Tissue Graft demonstrates minimal tissue attachment to the viscera when compared to a named predicate.

Conclusions Drawn from Tests:
The SURGISIS® Biodesign Tissue Graft is acting as its own predicate and is therefore substantially equivalent, having the same technological characteristics and intended use with the exception of the additional intended use, which is the subject of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cook Biotech, Inc.
% Mr. Perry W. Guinn
VP, Quality Assurance &
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1425 Innovation Place
West Lafayette, Indiana 47906-1000

MAR 21 2008

Re: K073391
Trade/Device Name: SURGISIS® Biodesign Tessue Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: February 26, 2008
Received: February 27, 2008

Dear Mr. Guinn:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **SURGISIS® Biodesign Tissue Graft**

Indications For Use:

The SURGISIS® Biodesign Tissue Graft is intended to be implanted to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect.

The SURGISIS® Biodesign Tissue Graft minimizes tissue attachment to the device in case of direct contact with viscera.

This device 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 K073391