K062697

1/2

Attachment 4

Special 510(k) Summary

Submitted by:

Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
Perry Guinn
VP Quality Assurance & Regulatory Affairs
Tel: (888) 299-4224 x 4942
FAX: (765) 497-2361

OCT 13 2006

September 15, 2006

Names of Device:
Trade Name: SIS Hernia Repair Device, Surgisis® Gold Hernia Repair Graft

Common/Usual Name: Surgical mesh

Proposed classification: Surgical mesh (79FTL)
21 CFR 878.3300
Class II

Performance standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act applicable to this device.

Intended use:

The SIS Hernia Repair Device is intended to be implanted to reinforce soft tissue where weakness exists. Indications for use include the repair of a hernia and body wall defect. The device is intended for one-time use.

Attachment 5

K062697
2/2

Summary of Substantial Equivalence:

The SIS Hernia Repair Device as described in this submission is substantially equivalent to its predicate with respect to the following characteristics:

Similarities:

1. Both have the same intended use.
2. Both use the same operating principles.
3. Both incorporate the same basic design.
4. Both incorporate the same materials.
5. Both have the same shelf-life.
6. Both pass the same set of internal tests and release criteria.
7. Both are packaged and sterilized using the same materials and processes.

Differences:

1. A process was changed that did not affect specifications or performance of the final device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2006

Cook Biotech Incorporated
% Mr. Perry W. Guinn
Vice President, Quality Assurance &
Regulatory Affairs
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K062697
Trade/Device Name: **SIS Hernia Repair Device**
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: September 14, 2006
Received: September 15, 2006

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.

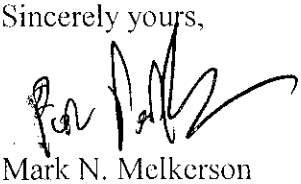
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 (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

K062697

Indications for Use

510(k) Number (if known):

Device Name: **SIS Hernia Repair Device**

Indications For Use:

The SIS Hernia Repair Device is intended to be implanted to reinforce soft tissue where weakness exists. Indications for use include the repair of a hernia or body wall defect. The device is intended for one-time use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K062697