DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2007

Cook Biotech Incorporated
% MED Institute, Inc.
Mr. Daniel J. Dillion
1400 Cumberland Avenue
West Lafayette, Indiana 47906

Re: K070405
Trade/Device Name: Modified SURGISIS® SLR™ Staple Line Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: July 31, 2007
Received: August 1, 2007

Dear Mr. Dillion:

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

K070405

Indications for Use

510(k) Number (if known): _____

Device Name: Modified SURGISIS® SLR™ Staple Line Reinforcement

Indications for Use: The SURGISIS® SLR™ Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. The device may be used for buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incisions and excisions of the lung and bronchus. The device can be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding, and for reinforcement of staple lines during small bowel, mesentery, colon, and colorectal procedures. The device may be used with anastomotic staplers or with non-anastomotic staplers. The device is supplied sterile and is intended for one-time use.

Prescription Use __XX___ AND/OR Over-the-Counter Use_____

(Per 21 CFR 801 Subpart D) (21 CRF 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

K070405

510(k) Number

510(k) SUMMARY

Submitted By: Perry Guinn, Vice President, Quality Assurance and Regulatory Affairs
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, IN 47906
(765) 412-6318
February 9, 2007

Name of Device:

Trade name:	SURGISIS® SLR™ Staple Line Reinforcement
Common/Usual Name:	Surgical Mesh
Proposed classification name:	Surgical Mesh 21 CFR 878.3300 (FTM) Class II

Intended Use:

The SURGISIS® SLR™ Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. The device may be used for buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incisions and excisions of the lung and bronchus. The device can be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding, and for reinforcement of staple lines during small bowel, mesentery, colon, and colorectal procedures. The device may be used with anastomotic staplers or with non-anastomotic staplers. The device is supplied sterile and is intended for one-time use.

Predicate Device:

The predicate device for the modified SURGISIS® SLR™ Staple Line Reinforcement is the SURGISIS® SLR™ Staple Line Reinforcement manufactured by Cook Biotech Incorporated (510(k) No. K051048), cleared for marketing on September 23, 2005.

Device Description:

The SURGISIS® SLR™ Staple Line Reinforcement device is produced from porcine small intestinal submucosa (SIS®) that has been disinfected and treated for surgical use. The modified

device is coated with an adhesive that eliminates the need for the application of a hydrogel to affix the device to the stapler arms. The device is supplied on a foam applicator, suspended in a form-fitting tray, and packaged in a sealed foil pouch to maintain sterility.

Substantial Equivalence:

The modified SURGISIS® SLR™ Staple Line Reinforcement is identical to the predicate SURGISIS® SLR™ Staple Line Reinforcement in terms of its indications. The results of performance bench and biocompatibility testing demonstrate substantially equivalent safety and effectiveness.

Discussion of Tests and Test Results:

The modified SURGISIS® SLR™ Staple Line Reinforcement device is substantially equivalent in its technological characteristics and performance testing to the predicate device. Furthermore, the device does not raise any new issues concerning patient safety.

Conclusions Drawn from the Tests:

The results of tests conducted on the modified device support its ability to act as a buttress for reinforcement of soft tissue staple lines in the same manner as the predicate. These conclusions support a decision of substantial equivalence to the predicate device.