K031069/p1

9. 510(K) SUMMARY

MAY 15 2003

Submitted By: Mark Bleyer, President
Cook Biotech Incorporated
3055 Kent Avenue
West Lafayette, IN 47906
(765) 497-3355
April 2, 2003

Names of Device:
Trade Name: SURGISIS® Nerve Cuff
Common/Usual Name: Nerve Cuff, Nerve Sheath
Proposed classification name: Nerve Cuff
21 CFR 882.5275 (84 JXI)
Class II

Intended Use:
The SURGISIS® Nerve Cuff is intended for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. The device is supplied sterile and is intended for one-time use.

Predicate Devices:
The SURGISIS® Nerve Cuff is similar to predicate devices, including the SURGISIS® Soft Tissue Graft (K980431) manufactured by Cook Biotech Incorporated, the NeuroGen Nerve Guide (K011168) manufactured by Integra Life Sciences, the SaluBridge Nerve Cuff (K002098) manufactured by Salumedica, LLC, and the Collagen Nerve Cuff (K012814) manufactured by Collagen Matrix Incorporated.

Device Description:
The SURGISIS® Nerve Cuff is manufactured from porcine small intestinal submucosa (SIS) and is supplied in nominal tube diameters of 2, 5 and 7 mm, and a nominal length of 5 cm. The device is packaged in a lyophilized (dried) state, and supplied sterile in a sealed double pouch system.

Substantial Equivalence:
The SURGISIS® Nerve Cuff 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 *in vitro* and *in vivo* testing.

Discussion of Tests and Test Results:
The material comprising the SURGISIS® Nerve Cuff was subjected to extensive biocompatibility testing, viral inactivation testing, mechanical testing, and assessment of in vivo performance. Outcomes show the device to be biocompatible, manufacturing processes to adequately disinfect the material, tensile strength to be sufficient as well as suture retention strength, ability to withstand compressive forces, and during *in vivo* use to be associated with a higher degree of axonal growth and myelination as compared to controls.

K031069/p2

Conclusions Drawn from the Tests:

Outcomes from the evaluation of the SURGISIS® Nerve Cuff provide evidence of its suitability for nerve cuff repair 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

MAY 15 2003

Mr. Mark Bleyer
President
Cook Biotech, Inc.
3055 Kent Avenue
West Lafayette, Indiana 47906

Re: K031069
Trade/Device Name: SURGISIS® Nerve Cuff
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve cuff
Regulatory Class: II
Product Code: JXI
Dated: April 2, 2003
Received: April 4, 2003

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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K03

K031069

Device Name: SURGISIS® Nerve Cuff

Indications For Use:

The SURGISIS® Nerve Cuff is intended for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. The device is supplied sterile and 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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031069

Prescription Use_____ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)