K132660

JAN 10 2014

510(k) Summary

January 10, 2014

Cook Biotech Incorporated

Nerve Cuff

Manufacturer Name: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, Indiana 47906
Telephone: +1 (765) 497-3355
FAX: +1 (765) 807-7709

Official Contact: Perry W. Guinn

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Nerve Cuff
Common Name:	Nerve Cuff
Classification Regulations:	Class II, 21 CFR §882.5275 (JXI)

INDICATIONS FOR USE:

The Nerve Cuff is indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity. The device is provided sterile and intended for one-time use.

DEVICE DESCRIPTION:

The Nerve Cuff is composed of a bioabsorbable, extracellular collagen matrix (Small Intestinal Submucosa, SIS). The SIS material that comprises the Nerve Cuff is identical to that of its predicate Nerve Cuff (K031069), also manufactured by Cook Biotech Incorporated. The Nerve Cuff is implanted providing a scaffold which becomes infiltrated by the patient's cells and is remodeled into native tissue. The Nerve Cuff provides protection of the damaged nerve while the nerve heals. The device is packaged in a dried state and supplied sterile in clamshell container inside a sealed double pouch system.

EQUIVALENCE TO MARKETED DEVICES

The Nerve Cuff is substantially equivalent with respect to intended use, materials and technological characteristics to its predicate Surgisis Nerve Cuff as shown through bench, biocompatibility and animal studies.

Bench testing:

Test	Results	Conclusions
Ultimate tensile strength	The tensile strength was comparable to Surgisis Nerve Cuff predicate	Substantially equivalent
Suture retention strength	The suture retention strength was comparable to the Surgisis Nerve Cuff	Substantially equivalent
Compression and rebound testing	Compression and rebound testing was performed on the predicate Surgisis Nerve Cuff. Since the Nerve Cuff is identical in material and configuration to the Surgisis Nerve Cuff, the results are applicable to the subject device's intended use.	Substantially equivalent
Hydration testing	Re-hydrated devices were compared to non-hydrated controls.	Devices were within the specified thickness range upon hydration

The results of these tests showed that the Nerve Cuff has sufficient tensile and suture retention strength for its application.

Biocompatibility testing:

Test	**Results**	**Conclusions**
Genotoxicity	Mouse micronucleus assay – results indicate that the test article is non-mutagenic in this system. Mouse lymphoma assay – results show that the test article extracts were well within the limits defined for a negative response and the test article is considered non-mutagenic in this assay.	Non-mutagenic
Direct contact in vitro hemolysis	Under conditions of the study, the mean hemolytic index of the test article was 2%.	Non-hemolytic
Cytotoxicity	Under the conditions of the study, the test extract showed no evidence of causing cell lysis or toxicity (less than Grade 2 – mild reactivity.	Non-cytotoxic
Muscle implantation	At 4, 12, nnd 24 weeks after implantation, the macroscopic reaction was not significant compared to control. At 4 and 12 weeks the test article was classified as a moderate irritant compared to the negative	Non-irritant at 24 weeks after implantation

Test	Results	Conclusions
	control (polyethylene). As compared to sponsor provided control 1(Dexon Mesh), the test article was classified as a slight irritant. As compared to sponsor provided control 2 (Supple Periguard), there was little or no difference. At 24 weeks after implantation, microscopy examination of implants sites revealed that the test article was similar to or less irritating than all the control materials.	
Acute intracutaneous reactivity	Under the conditions of the study, there was no evidence of significant irritation from the extracts injected intracutaneously into rabbits.	Non-irritant
Sensitization	Under the conditions of the study, the test article showed no evidence of causing delayed contact sensitization in the guinea pig.	Non-irritant
Acute systemic toxicity	Under the conditions of the study, there was no mortality or evidence of systemic toxicity from the extracts.	No systemic toxicity
Pyrogenicity	Under the conditions of the study, the total rise of rabbit temperatures during the 3 hour observation period was within acceptable USP limits.	Non-pyrogenic
LAL endotoxins	Under the conditions of the study, the endotoxin concentration for each article was less than 20 EU per device as required by FDA for devices in blood contact.	Non-pyrogenic
Subchronic systemic toxicity	Data and observations revealed no significant evidence of systemic toxicity from the test article following subcutaneous implantation in the rat. There were no changes in histopathology, hematology values or clinical chemistry values in either male or female rats that would be considered indicative of systemic changes related to treatment with the test article.	No systemic toxicity

The biocompatibility test results showed that the Nerve Cuff is safe and biocompatible and fulfills the ISO standard for a permanent, tissue contacting implant.

Animal studies

The Nerve Cuff was implanted in rabbits as a nerve wrap. The wrapped nerves were healthy in terms of myelination, density and vascularization compared to sham

controls. All assessments showed that the device is safe and effective as a nerve wrap. Therefore, results showed that the Nerve Cuff is biocompatible and safe in its application.

CONCLUSION: The Nerve Cuff is substantially equivalent to its predicate device in terms of safety and effectiveness as shown in bench and animal studies.

Table of Substantial Equivalence

Device	**Nerve Cuff**	**Surgisis Nerve Cuff**
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated
510(k) Number	K132660	K031069
Intended Use	Indicated for peripheral nerve injuries where there is no gap or where a gap closure is achieved by flexion of the extremity.	Intended for repair of peripheral nerve discontinuities where gap closure is achieved by flexion of the extremity.
Material	Porcine small intestinal submucosa Primarily Types I, III, IV and VI collagen	Porcine small intestinal submucosa Primarily Types I, III, IV and VI collagen
Dimensions	1.5 - 10 mm (diameter) x 1- 5 cm length	2, 5, 7 mm (diameter) x 5 cm length (nominal) (tubes)
Thickness	100 µm to 1000 µm	100 µm to 1000 µm
Sterilization	Ethylene oxide	Ethylene Oxide
Pliable	Yes	Yes
Wettable	Yes	Yes
Resorbable	Yes	Yes
Shelf-life	18 months	18 months
Packaging	Tray/Pouch or double pouch	Tray/Double-peel pouch

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 10, 2014

Cook Biotech Incorporated
% Mr. Perry W. Guinn
Vice President, Regulatory Affairs & Quality Assurance
1425 Innovation Place
West Lafayette, IN 47906-1000

Re: K132660
Trade/Device Name: Nerve Cuff
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: December 5, 2013
Received: December 9, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132660

Device Name: Nerve Cuff

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Prescription Use ✓ (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 Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S