DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 31, 2016

Cook Biotech Incorporated
Katrina Molland, PhD
Regulatory Affairs Specialist
1425 Innovation Place
West Lafayette, Indiana 47906

Re: K162741
Trade/Device Name: AxoGuard Nerve Connector
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: September 29, 2016
Received: September 30, 2016

Dear Dr. Molland:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162741

Device Name
AxoGuard Nerve Connector

Indications for Use *(Describe)*
The 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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) 497-3355
29 September, 2016

Name of Device:

Trade/Proprietary Names:	Nerve Cuff AxoGuard Nerve Connector
Common/Usual Names:	Cuff, Nerve
Product Code:	JXI
Device Class:	21 CFR §882.5275, Class II
Classification Panel:	Neurology

Predicate Device:
The predicate device is Surgisis Nerve Cuff (K031069), cleared May 15, 2003 and manufactured by Cook Biotech Incorporated.

Reference Device:
The reference device is the Nerve Cuff (K132660), cleared July 23, 2014 and manufactured by Cook Biotech Incorporated.

Intended Use:
The 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.

This intended use is identical to that of the predicate device cleared under K031069.

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 (Surgisis Nerve Cuff, K031069), and reference device (Nerve Cuff, K132660). Both the predicate and reference devices are also manufactured by Cook Biotech Incorporated. The Nerve Cuff is implanted around an injured nerve to provide a scaffold which becomes infiltrated by the patient's cells and is remodeled into native tissue. In addition, the Nerve Cuff protects the damaged or severed nerve while the nerve heals. The device is packaged in a dried state and supplied sterile in a clamshell container inside a sealed pouch.

Comparison to Predicate Device:
The Nerve Cuff is substantially equivalent with respect to intended use, materials and technological characteristics to its predicate, Surgisis Nerve Cuff. This Special 510(k) describes a size change to supply the Nerve Cuff in shorter lengths and one narrower diameter. The subject device is identical to the predicate with regard to intended use, indications for use, target population, anatomical site, use setting, performance, materials, compatibility with the environment and other devices, chemical safety, design, standards met, biocompatibility, and sterility. The subject device differs from the predicate device solely in regard to its dimensions as detailed in the Substantial Equivalence Table (**Table 5-5**).

The introduction of new device sizes does not affect substantial equivalence to the predicate device.

Comparison to Reference Device:
The size range of the reference device is identical to the expanded size range that forms the basis for this submission. The subject and reference (K132660) devices have a common predicate, the Surgisis Nerve Cuff (K031069). They are identical in material composition, and differ in design only with respect to a slit in the reference device. Their intended uses are nearly the same; the slit allows the reference device to be used where there is no gap in the injured nerve.

Summary of Non-Clinical Tests:
The functional performance verification and product characterization testing that was conducted on the subject device is provided in **Table 5-1**:

Table 5-1. Functional Performance Information

Test	Test Method Summary	Results
User handling validation	Surgeon handling of representative final product Acceptance criteria: product possesses acceptable characteristics for handling, trimming and suturing	The handling characteristics of the subject device are substantially equivalent to the predicate device based on acceptability to the end user. All samples met acceptance criteria.
Pre-clinical study discussion /evaluation of product line by key opinion leaders	Discussion of product line and surgeon handling of representative final product Acceptance criteria: No concerns regarding pre-clinical data and acceptable device handling characteristics	No concerns regarding pre-clinical data and the handling characteristics of the subject device are substantially equivalent to the predicate device based on acceptability to the end user. All samples met acceptance criteria.

Product characterization using known standards and/or clinically relevant acceptance criteria was performed on the predicate device. A summary of this testing is provided in **Table 5-2.** The predicate test data was leveraged to support the substantial equivalence of the subject device as the device material and manufacturing process is identical for the subject and predicate device.

Table 5-2. Bench Testing Information

Test	Test Method Summary	Results
Ultimate tensile strength	Testing according to ISO 7198:1990 and ISO 5081	The ultimate tensile strength of the material composing the subject device is greater than the predicate device.
Suture retention strength	Testing according to ISO 7198:1998	The suture retention strength of the material composing the subject device is sufficient to perform the intended use. All samples met acceptance criteria.
Compression and rebound	Devices were tested for maximum force required to collapse the tube and ability to rebound to original diameter	All samples met acceptance criteria with performance comparable to that of the predicate device.

Biocompatibility Testing:

Biocompatibility of the predicate device has been established in accordance with ISO 10993-1:2009 - *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* to demonstrate that the device is safe for permanent contact (>30 days) implantation as detailed in **Table 5-3**. The predicate test data was leveraged to support the substantial equivalence of the subject device as the device material and manufacturing process is identical for the subject and predicate device.

Table 5-3. Biocompatibility Information

Test	Test Method Summary	Results
Cytotoxicity	ISO 10993-5: Direct contact cytotoxicity following ISO elution	Pass Non-cytotoxic
Sensitization	ISO 10993-10: Maximization test in guinea pigs (sodium chloride and sesame oil extraction vehicles)	Pass No evidence of sensitization
Intracutaneous reactivity	ISO 10993-10: Intracutaneous reactivity test in rabbits (sodium chloride and sesame oil extraction vehicles)	Pass No evidence of intracutaneous reactivity
Acute systemic toxicity	ISO 10993-11: Acute systemic toxicity test in mice (sodium chloride and cottonseed oil extraction vehicles)	Pass No mortality or evidence of acute systemic toxicity
Subchronic and chronic toxicity	ISO 10993-11: Direct subcutaneous implant in rats for 4 weeks(subchronic) and 18 weeks (chronic)	Pass Non-irritating to subcutaneous tissue No evidence of subchronic or chronic toxicity
Genotoxicity	ISO 10993-3: Bacterial reverse mutation study	Pass Device extracts are non-mutagenic
Implantation	ISO 10993-6: Muscle implantation in rabbits for 4, 12, and 24 weeks	Pass Irritation not greater than control materials at 24 weeks

Sterilization:

The method employed to ensure sterility of the predicate device is provided in **Table 5-4.** The predicate test data was leveraged to support the substantial equivalence of the subject device as the device material and manufacturing process is identical for the subject and predicate device.

Table 5-4. Sterilization Information

Test	Test Method Summary	Results
Sterilization validation	Validation method in conformance with EN ISO 11135-2007 The validation of sterilization was performed using the over-kill method per guidelines outlined in sections 9.3.2 and 9.3.3 of the EN ISO 11135 standard.	Pass Devices have a sterility assurance level (SAL) of 10^{-6}

Substantial Equivalence:

Table 5-5 below provides a comparison of the subject device, its predicate and the reference device.

Table 5-5. Substantial Equivalence Information

Device	Nerve Cuff (Subject Device)	Surgisis Nerve Cuff (Predicate Device)	Nerve Cuff (Reference Device)
Manufacturer	Cook Biotech Inc.	Cook Biotech Inc	Cook Biotech Inc
510(k) number	unassigned	K031069	K132660
Product Code	JXI	JXI	JXI
Material	Porcine small intestinal submucosa; primarily collagen types ,I III, IV, and VI	Porcine small intestinal submucosa; primarily collagen types ,I III, IV, and VI	Porcine small intestinal submucosa; primarily collagen types ,I III, IV, and VI
Shape	Hollow tube	Hollow tube	Hollow tube with a slit
Supplied sterile?	Yes	Yes	Yes
Sterilization method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Intended for single use?	Yes	Yes	Yes
Packaging configuration	Clamshell tray in Tyvek pouch with an outer box	Clamshell tray in a double Tyvek pouch	Clamshell tray in Tyvek pouch with an outer box
Shelf Life	18 months	18 months	18 months
Intended Use	Intended for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.	Intended for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity	Intended 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.
Dimensions	1.5-10 mm diameter x 1-5 cm length	Diameter (mm): 2, 5, 7 / Length (cm): 5	1.5-10 mm diameter x 1-5 cm length
Thickness	100-1000 µm	100-1000 µm	100-1000 µm

Conclusion:

The Nerve cuff is substantially equivalent to its predicate device in terms of indications for use, methods of operation, and fundamental technological characteristics. Successful risk analysis and completion of verification and validation activities provides evidence to support the conclusion that the size modification does not introduce new risks and that the subject device performs comparably to the predicate device that is currently marketed for the same intended use.