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

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.

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

K132660

COOK BIOTECH INCORPORATED
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906-1000 U.S.A.
PHONE: 765.497.3355 TOLL FREE: 888.299.4224
WWW.COOKBIOTECH.COM

FDA CDRH DMC
AUG 26 2013
Received

August 23, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Device: **Nerve Cuff**
This Submission: **Traditional 510(k)**

Dear Sir/Madam,

The purpose of this letter is to notify the Food and Drug Administration, pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, that Cook Biotech Incorporated intends to market the Nerve Cuff. Cook Biotech Incorporated requests FDA review and clearance of this premarket notification submitted for the application of the Nerve Cuff. The device is intended for the repair of *peripheral nerve injuries in which there is no gap or where a gap closure can be achieved by flexion of the extremity.*

This 510(k) provides preclinical evidence that the Nerve Cuff is substantially equivalent to the predicate Cova ORTHO-NERVE (K103081) and is safe and effective as intended.

The following information pertaining to the Nerve Cuff is submitted:

1. Trade/Proprietary Names: Nerve Cuff

   Common/Usual Names: Nerve cuff

2. Establishment Name: Cook Biotech Incorporated

   Registration Number: 1835959

3. Proposed Classification: Nerve cuff (JXI)

   21 CFR §882.5275

   Class II

29

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

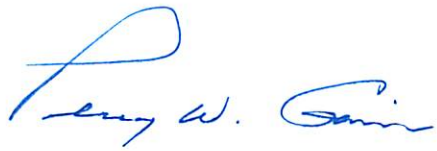
5. Two copies of this 510(k) Premarket Notification are included, one in electronic form. **The electronic copy is the exact duplicate of the paper submission.**

6. An RTA Checklist is provided in Section 22-*Other-RTA Checklist* to assist FDA in determining location of 510(k) elements.

The intent of Cook Biotech Incorporated to market this device is confidential commercial information. We request that it be considered as such by the FDA and not be available through Freedom of Information except where required by law. Cook Biotech Incorporated requests that the contents of the premarket notification submission be considered as company confidential for an indefinite time period. Unless prior permission from Cook Biotech Incorporated has been obtained, release to the public of any information that has been noted as company confidential will be considered a violation of company rights.

If you should have any questions concerning this premarket notification, please call me at (765) 497-3355 or email me at pguinn@cookbiotech.com.

Sincerely,



Perry W. Guinn

Vice President, Regulatory Affairs and Quality Assurance

PWG:maf

Enclosures

510(k) Premarket Notification

Nerve Cuff

Cook Biotech Incorporated

1425 Innovation Place

West Lafayette, IN 47906

+1.765.497.3355

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8. Financial Certification or Disclosure Statement (Not applicable)
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10. Executive Summary
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1. Medical Device User Fee Cover Sheet

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

COOK BIOTECH INC
1425 INNOVATION PLACE
WEST LAFAYETTE
IN 47906
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****0137

2. CONTACT NAME
Perry Guinn

2.1 E-MAIL ADDRESS
guinn@cookbiotech.com

2.2 TELEPHONE NUMBER (include Area code)
765-4973355 4942

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
765-8077709

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)Trade Secret 22-Aug-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

2. CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
Aug 23, 2013	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Cook Biotech Incorporated	Establishment Registration Number *(if known)*: 1835959		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 765-497-3355		
Street Address: 1425 Innovation Place	FAX Number *(including area code)*: 765-807-7709		
City: West Lafayette	State / Province: IN	ZIP/Postal Code: 47906	Country: USA
Contact Name: Perry W. Guinn			
Contact Title: VP/Quality Assurance and Regulatory Affairs	Contact E-mail Address: pguinn@cookbiotech.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name: Cook Biotech Incorporated			
Division Name *(if applicable)*:	Phone Number *(including area code)*: 765-497-3355		
Street Address: 1425 Innvoation Place	FAX Number *(including area code)*: 765-807-7709		
City: West Lafayette	State / Province: IN	ZIP Code: 47906	Country: USA
Contact Name: Mary A Faderan, Ph.D., RAC			
Contact Title: Regulatory Scientist	Contact E-mail Address: mfaderan@cookbiotech.com		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] New Device
- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Process change:
  - [ ] Manufacturing
  - [ ] Packaging
  - [ ] Sterilization
  - [ ] Other *(specify below)*

- [ ] Response to FDA correspondence:

- [ ] Change in design, component, or specification:
  - [ ] Software / Hardware
  - [ ] Color Additive
  - [ ] Material
  - [ ] Specifications
  - [ ] Other *(specify below)*

- [ ] Labeling change:
  - [ ] Indications
  - [ ] Instructions
  - [ ] Performance Characteristics
  - [ ] Shelf Life
  - [ ] Trade Name
  - [ ] Other *(specify below)*

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

- [ ] Report Submission:
  - [ ] Annual or Periodic
  - [ ] Post-approval Study
  - [ ] Adverse Reaction
  - [ ] Device Defect
  - [ ] Amendment

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - [ ] Correspondent / Applicant
  - [ ] Design / Device
  - [ ] Informed Consent
  - [ ] Manufacturer
  - [ ] Manufacturing Process
  - [ ] Protocol - Feasibility
  - [ ] Protocol - Other
  - [ ] Sponsor

- [ ] Report submission:
  - [ ] Current Investigator
  - [ ] Annual Progress Report
  - [ ] Site Waiver Report
  - [ ] Final

- [ ] Response to FDA Letter Concerning:
  - [ ] Conditional Approval
  - [ ] Deemed Approved
  - [ ] Deficient Final Report
  - [ ] Deficient Progress Report
  - [ ] Deficient Investigator Report
  - [ ] Disapproval
  - [ ] Request Extension of Time to Respond to FDA
  - [ ] Request Meeting
  - [ ] Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	JXI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K031069	1	Surgisis Nerve Cuff	1	Cook Biotech Inc.
2	K103081	2	Cova ORTHO-NERVE	2	Biom' Up
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Nerve cuff

	Trade or Proprietary or Model Name for This Device		Model Number
1	Nerve Cuff	1	To be determined
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [x] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
JXI	21 CFR 882.5275	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Neurology

Indications *(from labeling)*

The Nerve Cuff is indicated for 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 is intended for one-time use.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 3002340648	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name Cook Biotech Incorporated		Establishment Registration Number 1835959		
Division Name *(if applicable)*		Phone Number *(including area code)* 765-497-3355		
Street Address 1425 Innovation Place		FAX Number *(including area code)* 765-807-7709		
City West Lafayette		State / Province IN	ZIP Code 47906	Country USA
Contact Name Perry W. Guinn	Contact Title VP/Quality Assurance and Regulatory Affairs		Contact E-mail Address pguinn@cookbiotech.com	

(b)(4)Trade Secret Process

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	11135-1	EN	Sterilization of Health Care Products - Ethylene Oxide - Part I: Requirements for development, validation and routine control of a sterilization process for medical devices	2007	01/01/2007
2	10993-1	ANSI/AAMI/ISO	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing	2009	01/01/2009
3	10993-3	ANSI/AAMI/ISO	Biological Evaluation of Medical Devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2009	01/01/2009
4	10993-4	ANSI/AAMI/ISO	Biological Evaluation of Medical Devices - Part 4: Selection of tests for interactions with blood	2002	01/01/2002
5	10993-5	ANSI/AAMI/ISO	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity, in vitro methods	2009	01/01/2009
6	10993-6	ANSI/AAMI/ISO	Biological Evaluation of Medical Devices - Part 6: Tests for local effects after implantation	2007	01/01/2007
7	10933-7	ANSI/AAMI/ISO	Biological Evaluation of Medical Devices - Part 7: Ethylene oxide sterilization residuals	2008	01/01/2008

Please include any additional standards to be cited on a separate page.

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

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Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
8	10993-10	ANSI/AAMI/ ISO	Biological Evaluation of Medical Devices – Part 10: Tests for irritation and delayed-type hypersensitivity	2002	2002
9	10993-11	ANSI/AAMI/ ISO	Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity	2006	2006
10	1798	ISO	Flexible Cellular Materials – Determination of Tensile Strength and Elongation at Break	2008	2008
11	7198	ANSI/AAMI/ ISO	Cardiovascular Implants –Vascular Prostheses	1998	1998
12	13934	ISO	Textiles – Tensile Properties of Fabrics Part I- Determination of maximum force and elongation at maximum force using the strip method	1999	1999
13					
14					

Please include any additional standards to be cited on a separate page.

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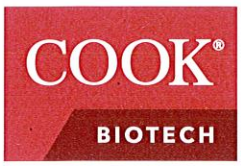
3. 510(k) Cover Letter



COOK BIOTECH INCORPORATED
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906-1000 U.S.A.
PHONE: 765.497.3355 TOLL FREE: 888.299.4224
WWW.COOKBIOTECH.COM

August 23, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Device: **Nerve Cuff**
This Submission: **Traditional 510(k)**

Dear Sir/Madam,

The purpose of this letter is to notify the Food and Drug Administration, pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, that Cook Biotech Incorporated intends to market the Nerve Cuff. Cook Biotech Incorporated requests FDA review and clearance of this premarket notification submitted for the application of the Nerve Cuff. The device is intended for the repair of *peripheral nerve injuries in which there is no gap or where a gap closure can be achieved by flexion of the extremity.*

This 510(k) provides preclinical evidence that the Nerve Cuff is substantially equivalent to the predicate Cova ORTHO-NERVE (K103081) and is safe and effective as intended.

The following information pertaining to the Nerve Cuff is submitted:

1. Trade/Proprietary Names: Nerve Cuff

   Common/Usual Names: Nerve cuff

2. Establishment Name: Cook Biotech Incorporated

   Registration Number: 1835959

3. Proposed Classification: Nerve cuff (JXI)

   21 CFR §882.5275

   Class II

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

5. Two copies of this 510(k) Premarket Notification are included, one in electronic form. **The electronic copy is the exact duplicate of the paper submission.**

6. An RTA Checklist is provided in Section 22-*Other-RTA Checklist* to assist FDA in determining location of 510(k) elements.

The intent of Cook Biotech Incorporated to market this device is confidential commercial information. We request that it be considered as such by the FDA and not be available through Freedom of Information except where required by law. Cook Biotech Incorporated requests that the contents of the premarket notification submission be considered as company confidential for an indefinite time period. Unless prior permission from Cook Biotech Incorporated has been obtained, release to the public of any information that has been noted as company confidential will be considered a violation of company rights.

If you should have any questions concerning this premarket notification, please call me at (765) 497-3355 or email me at pguinn@cookbiotech.com.

Sincerely,

Perry W. Guinn

Vice President, Regulatory Affairs and Quality Assurance

PWG:maf

Enclosures

4. Indications for Use Statement

Indications for Use

510(k) Number (if known):

Device Name: Nerve Cuff

Indications For Use: The Nerve Cuff is indicated for 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 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)

Page 1 of _____

5. 510(k) Summary

510(k) Summary

August 23, 2013

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 and similar to its other predicate, Cova ORTHO-NERVE (K103081) manufactured by Biom' Up S.A (France). 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 predicates Surgisis Nerve Cuff and Cova ORTHO-

NERVE, as shown through bench and animal studies, biocompatibility testing and clinical studies:

Bench testing:

- Ultimate tensile strength
- Suture retention strength
- Compression and rebound testing

Biocompatibility testing:

- Genotoxicity
- Direct contact *in vitro* hemolysis
- Cytotoxicity
- Muscle implantation
- Acute intracutaneous reactivity
- Sensitization
- Acute systemic toxicity
- Pyrogenicity
- LAL endotoxins
- Subchronic systemic toxicity

Animal studies

The Nerve Cuff was implanted in rabbits as a nerve wrap. The results showed that the Nerve Cuff is biocompatible and safe in its application.

CONCLUSION: The Nerve Cuff is substantially equivalent to its predicate devices in terms of safety and effectiveness.

Table of Substantial Equivalence

Device	**Nerve Cuff**	**Surgisis Nerve Cuff**	**Cova ORTHO-NERVE**
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated	Biom' Up SA
510(k) Number	Not assigned	K031069	K103081
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.	Indicated for peripheral nerve injuries where there is no gap or where a 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	Porcine collagen
Dimensions	1.5 - 10 mm (diameter) x 1- 5 cm length (slit tubes) and sheets of sizes 15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm	2, 5, 7 mm (diameter) x 5 cm length (nominal) (tubes)	15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm sheets
Thickness	100 µm to 1000 µm	100 µm to 1000 µm	NA

6. Truthful and Accuracy Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*
(As Required By 21 CFR 807.87(j))

I certify that, in my capacity as Vice President of Regulatory Affairs and Quality Assurance of Cook Biotech Incorporated, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

[*Signature*]

Perry W. Guinn, VP of Regulatory Affairs and Quality Assurance
[Typed Name and Title]

Cook Biotech Incorporated 23 Aug 2013

[Company] [Date]

[*Premarket Notification (510(k)) Number*]

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

7. Class III Summary and Certification

(Not applicable)

8. Financial Certification or Disclosure Statement
(Not applicable)

9. Declarations of Conformity and Summary Reports

(Reference to Special Controls)

Declarations of Conformity and Summary Reports

(Reference to Special Controls)

Performance Standards

No performance standards applicable to the Nerve Cuff have been established by FDA.

Voluntary Standards

EN 11135 *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ANSI/AAMI/ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing*

ANSI/AAMI/ISO 10993-3 *Biological Evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

ANSI/AAMI/ISO 10993-4 Biological Evaluation of Medical Devices – Part 4: Selection of tests for interaction with blood

ANSI/AAMI/ISO 10993-5 *Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity, in vitro methods*

ANSI/AAMI/ISO 10993-6 *Biological Evaluation of Medical Devices – Part 6: Tests for local effects after implantation*

ANSI/AAMI/ISO 10993-7 *Biological Evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals*

ANSI/AAMI/ISO 10993-10 *Biological Evaluation of Medical Devices – Part 10: Tests for irritation and delayed-type hypersensitivity*

ANSI/AAMI/ISO 10993-11 *Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity*

ANSI/AAMI/ISO 22442-02 Medical Devices Utilizing Animal Tissues and their derivatives – Part 2: Control on sourcing, collection and handling

ISO 1798 *Flexible Cellular Materials – Determination of Tensile Strength and Elongation at Break*

AAMI/ANSI/ISO 7198 *Cardiovascular Implants – Tubular Vascular Prostheses*

ISO 13934 *Textiles – Tensile properties of fabrics – Part 1: Determination of Maximum Force and Elongation at Maximum Force Using the Strip Method*

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EN 11135 (2007): Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for development, validation...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-228	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EN11135 (2007): Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements of development, validation...

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.3.2	Performance qualification - microbiological	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION
Validation of sterilization was performed using the over-kill method per guidelines outlined in this section.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.3.3	Performance qualification - physical	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION
Validation of sterilization was performed using the over-kill method per guidelines outlined in this section.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 10993 - 1 (2003): Biological evaluation of medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Use of ISO 10993: Biological Evaluation of Medical Devices

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO - 10993 - 1 (2003): Biological evaluation of medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Selection of biological evaluation tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Parts 3, 4, 5, 6, 7, 10 and 11

DESCRIPTION
Tests for permanent implant in tissue/bone

JUSTIFICATION
Appropriate selection of tests for duration, device type and tissue exposure

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION
Validation of sterilization was performed using the over-kill method per guidelines outlined in this section.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 10993 - 3 (2003): Tests for genotoxicity, carcinogenicity and reproductive toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-117	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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Title of guidance: Use of ISO 10993: Biological Evaluation of Medical Devices

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO - 10993 - 3 (2003): Tests for genotoxicity, carcinogenicity and reproductive toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Genotoxicity tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
4.2.4 (a) Micronucleus tests (OECD 474)

DESCRIPTION
Evaluation of potential of SIS to induce micronucleus formation in immature polychromatic erythrocytes in bone marrow in mice.

JUSTIFICATION
"In vivo testing shall be performed in accordance to ISO 10993-3."

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Genotoxicity tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
4.2.1.1 (b) A test for gene mutations in mammalian cells (OECD 476)

DESCRIPTION
Evaluation of potential of SIS to induce mutations in TK gene of L5178Y cells.

JUSTIFICATION
See 4.2.2 above

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 10993 - 4 (2002): Biological evaluation of medical devices - Selection of tests for interaction with blood

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Is there an FDA guidance [6] that is associated with this standard?	☒	☐
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Title of guidance: Use of ISO 10993: Biological Evaluation of Medical Devices

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO - 10993 - 4 (2002): Biological evaluation of medical devices - Selection of tests for interaction with blood

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.3.1	In Vitro tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Annex C: Evaluation of hemolytic properties of medical devices and their components

DESCRIPTION
Whole rabbit red blood cells were added to test article in saline in order to determine if hemolysis occurs.

JUSTIFICATION
Hemolysis testing of medical devices has historically been used to measure blood compatibility in vitro.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 10993 - 5 (2009): Biological evaluation of medical devices - Tests for In Vitro cytotoxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO - 10993 - 5: Tests for In Vitro Cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.2	Tests on extracts	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
8.2.5 (a) and 8.2.5 (b) - Perform tests on original extract and dilution series of extract

DESCRIPTION
See previous entry

JUSTIFICATION
8.2.1 "This test allows both quantitative and qualitative assessment of cytotoxicity.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 10993 - 6 (2007): Biological evaluation of medical devices - Test for local effects after implantation

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-120	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO - 10993 - 6: Tests for local effects after implantation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex C	Test method for implantation in muscle	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
5.3 Test periods

DESCRIPTION
Test article implanted in muscle tissue of the rabbit terminating at 4, 12 and 24 weeks.

JUSTIFICATION
A sufficient number of implants shall be inserted to insure that the final number of specimens evaluated give valid results.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 10993 - 7 (2008): Biological evaluation of medical devices - Ethylene oxide sterilization residuals

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-279	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO - 10993 - 7: Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 7	Ethylene oxide sterilization residuals	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
4.4.6.2 Exhaustive extraction (acceptable alternative method)

DESCRIPTION
Different sizes of test articles were extracted with sterile water for 24 hrs at 37 deg C under exhaustive conditions

JUSTIFICATION
annex E Extraction condition for determination of residual ethylene oxide

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE [1]

ISO - 10993 - 10 (2002): Biological evaluation of medical devices -Tests for irritation and delayed-type hypersensitivity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-152	
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO - 10993 - 10: Biological evaluation of medical devices - Part 10: Tests for irritation and delayed type hypersensitivity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.3	Animal skin irritation tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
6.3.3 Animals and husbandry

DESCRIPTION
A 1" x 1" section of the test article was topically applied to skin on rabbit and left in place for 4 hrs.

JUSTIFICATION
Demonstration of sensitivity to test article.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.4	Maximization test for delayed hypersensitivity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
7.4.4 Test procedure - injection and use of occlusive patch

DESCRIPTION
Response, pattern, character & duration of any test animal reaction were assessed in ability of SIS to elicit allergic reaction.

JUSTIFICATION
Assess potential of SIS to produce skin irritation.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex B	Additional irritation tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
B2.5 Test procedure - intracutaneous (intradermal) reactivity test

DESCRIPTION
Extracts of SIS was injected by intracutaneous route in guinea pigs

JUSTIFICATION
B.1 - "These tests are only relevant for medical devices to be applied to these specific areas."

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 10993 - 11 (2006): Biological evaluation of medical devices -Tests for systemic toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO - 10993 - 11: Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex A.8	Acute intravenous application	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Acute intravenous application

DESCRIPTION
Saline extracts of test article were injected intravenously into mice.

JUSTIFICATION
Tests for systemic toxicity by i.v. route may be appropriate for device with fluid path...environment,...chemical leaching.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex A.7	Acute intraperitoneal application	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Acute intraperitoneal application

DESCRIPTION
Sesame oil extracts of test article were injected i.p. into mice.

JUSTIFICATION
...may be appropriate for devices with fluid path or peritoneal cavity contact environment conducive to chemical leaching.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex F	Information on material mediated pyrogens	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Testing for pyrogenic substances of either endotoxin or non-endotoxin origin.

DESCRIPTION
To determine whether test solution induces pyrogenic response following i.v. injection of rabbit.

JUSTIFICATION
Pyrogenic responses may be material-mediated, endotoxin mediated or mediated by other substances.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 10993 - 11 (2006): Biological evaluation of medical devices -Tests for systemic toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Use of ISO 10993: Biological Evaluation of Medical Devices

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO - 10993 - 11: Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex F	Information on material mediated pyrogens	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Endotoxin-mediated pyrogenicity

DESCRIPTION
A limulus amebocyte lysate (LAL) test as an end-point endotoxin test was conducted on test article.

JUSTIFICATION
Pyrogenicity testing should be considered in evaluation of medical device/materials.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Section 6.7	Repeated exposure - Subchronic systemic toxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Subchronic dermal application

DESCRIPTION
Evaluation of potential test article to cause systemic toxicity and/or irritation following SQ implantation in rat (up to 18 weeks).

JUSTIFICATION
The rat is suggested in ISO Standard and OECD guidelines as acceptable animal model for evaluating potential toxicity of material.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 1798 (2008) Flexible cellular materials - Determination of Tensile Strength and Elongation at Break

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: Guidance document for Vascular Prostheses 510(k) Submissions

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 7198 (1998) Cardiovascular implants - Tubular Vascular Prostheses

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#3-54	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
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If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: Guidance document for Vascular Prostheses 510(k) Submissions

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 7198 (1998): Cardiovascular Implants - Vascular Prostheses

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.8	Method of determination of suture retention strength	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 1798 (2008) Flexible cellular materials - Determination of Tensile Strength and Elongation at Break

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] #		
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Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 13934 (1999) Textiles - Tensile Properties of Fabrics Part 1 -Determination of maximum force and elongation...strip method

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☒	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 13934 (1998) Textiles - Tensile properties of fabrics

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Specimens	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Adaptation of extracellular membrane (small intestinal submucosa).

DESCRIPTION
Extracellular membrane (small intestinal submucosa) was used as a specimen.

JUSTIFICATION
The standard described strength and elongation test for wet specimens which was adapted for the small intestinal submucosa.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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10. Executive Summary

Executive Summary

The Nerve Cuff is a bioabsorbable, extracellular collagen matrix that is identical in terms of its base material to its SIS predicate Surgisis Nerve Cuff (K031069) also manufactured by Cook Biotech Incorporated, and similar in terms of being a collagen implant to Cova ORTHO-NERVE (K103081) manufactured by Biom' Up S.A. This premarket notification is being submitted in order to support the substantial equivalence of the Nerve Cuff to its predicates Surgisis Nerve Cuff and Cova ORTHO-NERVE for the repair of peripheral nerve injuries where there is no gap or where gap closure is achieved by flexion of the extremity. In particular, this premarket notification submits preclinical evidence for its Nerve Cuff device which is a tube with a premade slit, or a flat sheet. The Nerve Cuff device will be available and have a range of sizes (diameters and lengths) in a slit tube configuration as well as in the sheet configuration.

Intended Use

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

Device Description

The Nerve Cuff is manufactured from porcine small intestine that has been (b)(4)Trade Secret Process [redacted] The resulting acellular collagenous layer, which is termed Small Intestinal Submucosa (SIS), is packaged in a dried state.

The material composition of the Nerve Cuff is unchanged compared to the material composition described for its predicate, the Surgisis Nerve Cuff. Please refer to the Device Master File (b)(4)Trade Secret Process for additional details regarding composition. The Nerve Cuff is composed of multiple layers of SIS sheets. It will have nominal thickness ranging from 100 µm to 1000 µm and sizes ranging 1.5 to 10 mm in diameter and from 1 to 5 cm in length (slit tubes). The Nerve Cuff will also be available in sheet forms with dimensions of 15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm. Please refer to Section 11 – *Device Description* for images of the Nerve Cuff.

The Nerve Cuff will be manufactured by Cook Biotech Incorporated, 1425 Innovation Place, West Lafayette, Indiana, 47906. The processes used to manufacture the Nerve Cuff are unchanged compared to those outlined in its cleared 510(k) for its predicate device, Surgisis Nerve Cuff (K031069), except for a change in casing/disinfecting steps (submitted in K061711) of the SIS base material.

Viral Inactivation

The viral inactivation process used for the Nerve Cuff is identical to that used for the Surgisis Nerve Cuff but differs slightly in terms of manufacturing steps originally described in the K031069 submission. The process change (b)(4)Trade Secret Process [redacted] was determined to not pose a risk to the viral inactivation validation referenced therein. Please refer to the Device Master File (b)(4)Trade Secret Process for the reports describing the validation testing.

Sterilization

The Nerve Cuff will be sterilized using an established ethylene oxide (EO) sterilization cycle that has been validated to a sterility assurance level (SAL) of 10^{-6} in conformance with ISO 11135 – 2007: *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*. Using the exhaustive extraction technique, the EO sterilization residuals have been verified to be less than the maximum allowable limits (4 mg for ethylene oxide and 9 mg for ethylene chlorohydrin) as defined in ISO 10993-7 – 2008 *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*. Please see Section 14 – *Sterilization* for details about the sterilization process for the Nerve Cuff.

Packaging and Shelf-life

The packaging of the Nerve Cuff is unchanged compared to the packaging, storage, and shelf-life described in the 510(k) for the Surgisis Nerve Cuff (K031069). The Nerve Cuff will be packaged using a clamshell container inside a pouch system that allows transfer of the inner container, which is sterile, into the sterile field. The outer pouch consists of polyester-polyethylene film with Tyvek® backing that forms a pouch. After packaging, the Nerve Cuff will be transported for sterilization and labeled. Please see Section 13 – *Proposed Labeling* for a representative draft of the outer package labeling.

Shelf-life of the SIS material comprising the Nerve Cuff has been established at a minimum of 18 months (b)(4)Trade Secret Process [redacted]

(b)(4)Trade Secret [redacted] Please see Section 14 – *Sterilization* for details about packaging and shelf life testing of the Nerve Cuff.

Biocompatibility

Biocompatibility of the Nerve Cuff has been demonstrated by conducting a full range of testing in conformance with ISO 10993 *Biological evaluation of medical devices*, using terminally sterilized SIS, which comprises the material in both the Nerve Cuff and its predicate, Surgisis Nerve Cuff. Based on the results of this testing, it was concluded that the Nerve Cuff is biocompatible as a permanent implant device. Please see Section 15 – *Biocompatibility* for results of the biocompatibility testing for the Nerve Cuff.

Performance Testing – Bench

Section 18 – *Performance Testing – Bench* contains data for finished devices that were tested for mechanical strength, including ultimate tensile strength and suture retention strength. The data show that the Nerve Cuff has adequate mechanical strength for this application.

Performance Testing – Animal

Section 19 – *Performance Testing – Animal* includes a study conducted in rabbits in a nerve wrap application.

Substantial Equivalence

The Nerve Cuff has a similar intended use as its predicate Surgisis Nerve Cuff, manufactured by Cook Biotech Incorporated; and identical intended use as its other predicate Cova ORTHO NERVE manufactured by Biom' UpSA. With respect to technology, the porcine derived, acellular, collagenous tissue comprising the Nerve Cuff is identical to that of Surgisis Nerve Cuff and similar to the ORTHO-NERVE device. Please refer to Table 10-1 comparing the intended use and technological characteristics of the Nerve Cuff to the predicate devices supporting 510(k) substantial equivalency, and to Section 12 – *Substantial Equivalence Discussion* for product information on these predicate devices.

Table 10-1: Summary of Substantial Equivalence

Device	**Nerve Cuff**	**Surgisis Nerve Cuff**	**Cova ORTHO NERVE**
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated	Biom' Up SA
510(k) Number	Not assigned	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.	Indicated for peripheral nerve injuries where there is no gap or where a 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	Collagen
Dimensions	1.5 - 10 mm (diameter) x 1- 5 cm length (slit tubes) and sheets of sizes 15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm	2, 5, 7 mm (diameter) x 5 cm length (nominal)	15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm sheets
Thickness	100 µm to 1000 µm	100 µm to 1000 µm	NA

11. Device Description

Device Description

The Nerve Cuff is a bioabsorbable, extracellular collagen matrix that is identical in material composition to its predicate Surgisis Nerve Cuff (K031069), also manufactured by Cook Biotech Incorporated; and similar in composition to its other predicate, Cova ORTHO-NERVE (K103081), manufactured by Biom' Up, SA.

Indications for Use

The Nerve Cuff is indicated for peripheral nerve injuries where there is no gap or where a gap closure is achieved by flexion of the extremity.

Materials and Configuration

The Nerve Cuff is derived from porcine small intestinal submucosa (SIS). The device is available both as a as a multi-layered flat sheet, and a tube that contains a slit enabling the surgeon to implant the device around an injured, but not severed nerve.

Configuration

The Nerve Cuff is provided in sizes ranging from 1.5 to 7 mm in diameter and from 1-5 cm in length in a slit tube configuration. The sheet form will have dimensions from 15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm. The device will have a nominal thickness ranging from 100 µm to 1000 µm.

Figures 11-1 and 11-2 show representative images of the Nerve Cuff.

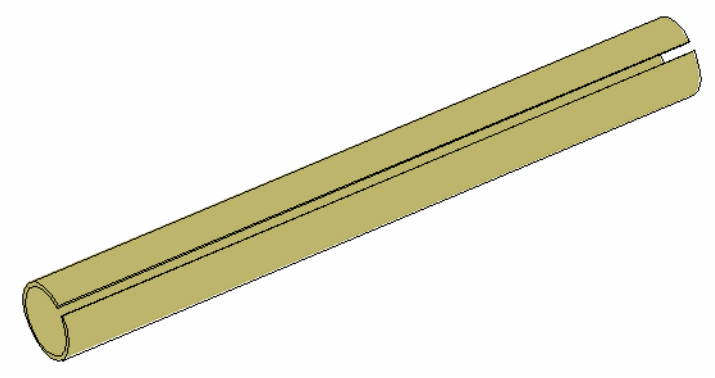


Figure 11-1: Tube with slit Image of the Nerve Cuff

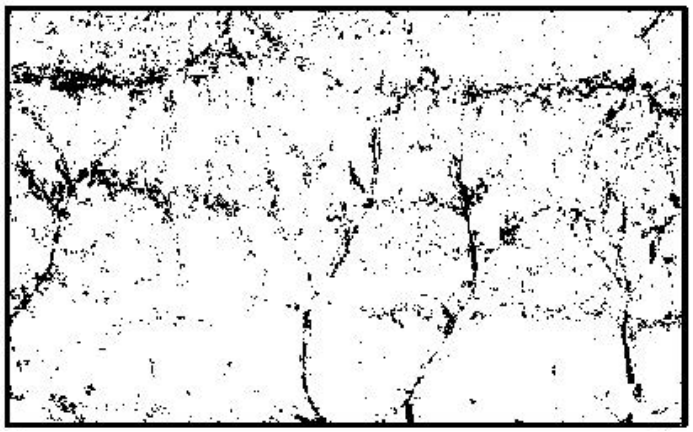


Figure 11-2: Sheet image of the Nerve Cuff

Material Composition

The Nerve Cuff is manufactured from (b)(4)Trade Secret Process [redacted] The resulting

acellular, collagenous layer, which is termed small intestinal submucosa (SIS), is packaged in a dried state. Please refer to the Device Master File MAF-1036, Series 2000, Section 2001, for additional details regarding composition.

Viral Inactivation

The viral inactivation process of the Nerve Cuff is identical to that used for the predicate Surgisis Nerve Cuff but differs from the process originally described in the K031069 submission. A process change in (b)(4)Trade Secret Process [redacted] was included in a 510(k) cleared by FDA (K061711). This change was implemented to streamline the manufacturing process for SIS and improve product consistency. Please refer to the Device Master File (b)(4)Trade Secret Process [redacted] which reports viral inactivation validation for the SIS material comprising the Nerve Cuff.

Packaging

Similar to the predicate Surgisis Nerve Cuff, the Nerve Cuff will be packaged in a clam-shell container (for the slit tube) inside a pouch system that allows transfer of the inner container, which is sterile, into the sterile field. The flat sheet configuration of the Nerve Cuff will be placed inside an inner pouch within the sterile outer pouch. The outer pouch consists of polyester-polyethylene film with Tyvek® paper backing that forms a pouch. After packaging, the Nerve Cuff will be transported for sterilization and labeled. Please see Section 13 – *Proposed Labeling* for a draft of the outer package labeling.

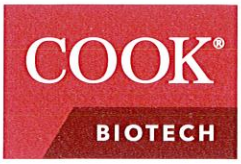
The shelf-life of the Nerve Cuff is the same as that of the Surgisis Nerve Cuff, which has been established at a minimum of 18 months. The 18 month shelf-life is based on real-time testing of finished samples of SIS material, which is identical to the Nerve Cuff in composition and packaging material, out to 22 months. Please refer to MAF-1036, Series 1000, Section 1032 for the report describing this testing.

Results of this testing provide reasonable assurance the Nerve Cuff will maintain sterility and performance characteristics following at least 18 months of storage.

Mode of Operation

The Nerve Cuff is rehydrated with sterile saline or lactated Ringer's solution and applied to the defect. The device can be trimmed by the surgeon before it is affixed around the injured nerve using standard surgical procedures. Please refer to Section 13 – *Proposed Labeling* for the Draft Instructions for Use of the Nerve Cuff.

Letter Granting Access to Master File



COOK BIOTECH INCORPORATED
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906-1000 U.S.A.
PHONE: 765.497.3355 TOLL FREE: 888.299.4224
WWW.COOKBIOTECH.COM

August 23, 2013

Medical Device Reviewer
Office of Device Evaluation – 510(k)
Document Mail Center WO66-G609
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Nerve Cuff

Dear FDA Reviewer:

This letter hereby authorizes the Food and Drug Administration to incorporate by reference the Device Master Files MAF-955, Sections 3010 and 3011 and MAF-1036 Section 1001, 1002, 1032, 2001, 3007, 3008, 3010, 3011, 3017, 3062, 3065, 3074, and 4043 for the purpose of review for substantial equivalence by the CDRH, Office of Device Evaluation of a premarket notification for the Nerve Cuff.

Sincerely,

Perry W. Gunn
VP Regulatory Affairs and Quality Assurance

PWG:maf

12. Substantial Equivalence Discussion

Substantial Equivalence Discussion

Cook Biotech Incorporated submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the Nerve Cuff is substantially equivalent in indications and technological characteristics to the following predicate devices: Surgisis® Nerve Cuff (K031069) also manufactured by Cook Biotech, Incorporated, and Cova ORTHO-NERVE (K103081), manufactured by Biom' Up, SA.

The intended use, design, materials and functional characteristics of the Nerve Cuff and its predicate devices Surgisis Nerve Cuff and Cova ORTHO NERVE are substantially equivalent.

The Nerve Cuff, Surgisis Nerve Cuff, and Cova ORTHO-NERVE are all generally intended for use in repairing injured nerves. In particular, the Nerve Cuff and Cova ORTHO NERVE devices have identical intended uses.

The Nerve Cuff and Surgisis Nerve Cuff have identical materials, and, together with the Cova ORTHO-NERVE, have similar technological and functional characteristics.

The subject device and its predicates are collagen-based devices that are implants and are resorbable. The material composition of the Nerve Cuff is identical to that of the Surgisis Nerve Cuff. Both of these devices are made from collagen (predominantly Types I and III as well as Types IV and VI) derived from porcine small intestinal submucosa (SIS). The Cova ORTHO-NERVE is also made of collagen, and is also derived from a porcine source.

Overall, the Nerve Cuff has the following similarities to the predicate devices:

- Similar intended use
- Same basic design
- Similar materials, and
- Identical operating principles

Animal studies using the Nerve Cuff show that this device is substantially equivalent to the Cova ORTHO-NERVE in terms of operating principles.

The 510(k) Substantial Equivalence Decision-Making Process as outlined in ODE Guidance Document No. K86-3, *Guidance on the CDRH Premarket Notification Review Program*, was used to determine substantial equivalence. The answers to the following questions from the guidance lead to a determination that the Nerve Cuff is substantially equivalent to its predicates Surgisis Nerve Cuff and Cova ORTHO-NERVE:

1) **Does the new device have the same indication statements?**
   Yes, the Indications for Use statement of the Nerve Cuff is the same as that of the Cova ORTHO-NERVE and similar to that of the Surgisis Nerve Cuff.
2) **Do the differences alter the intended therapeutic/diagnostic, etc. effect (in deciding, may consider impact on safety and effectiveness)?**
   No. The impact on safety and effectiveness are the same. The Nerve Cuff and its predicates all provide nerve repair.
3) **Does the new device have the same technological characteristics, e.g. design, materials, etc.?**
   Yes. The Nerve Cuff has similar technological characteristics as its predicates. Like the Surgisis Nerve Cuff, it is made from the same base material, SIS. Like its predicate, Cova ORTHO-NERVE, it is implanted in a similar manner. Like both predicates it has a similar technological function where the device is gradually remodeled by the host tissue as cells populate the collagen scaffold.
4) **Could the new characteristics affect safety and effectiveness?**

No. The Nerve Cuff possesses the same characteristics as its predicates, thus not affecting safety and effectiveness of the device.

5) **Do the new characteristics raise new types of safety and effectiveness questions?**

   No. The overall issues of safety and effectiveness associated with the Nerve Cuff are the same as those associated with predicates. Like its predicates, the Nerve Cuff exhibits similar biocompatibility, mechanical strength and ability to be reabsorbed by the body. This premarket notification contains the evidence for its safety and effectiveness in terms of biocompatibility and mechanical strength.

6) **Do accepted scientific methods exist for assessing effects of the new characteristic?**

   Yes. The same mechanical, bench, animal and clinical tests exist for assessing the Nerve Cuff (see *Performance Testing – Bench, – Animal*, in this submission). These tests have been performed on the previously cleared Surgisis Nerve Cuff device.

7) **Are performance data available to assess effects of the new characteristic?**

   Yes. Sections 18 (Bench) and 19 (Animal) provide performance data to assess the effects of the Nerve Cuff.

8) **Do performance data demonstrate equivalence?**

   Yes. All the performance data demonstrate equivalence of the Nerve Cuff to its predicates.

In summary, the Nerve Cuff is substantially equivalent to the predicate devices. The basis for this conclusion is summarized in the following table (see Table 12-1).

Table 12-1: Summary of Substantial Equivalence

Device	Nerve Cuff	Surgisis Nerve Cuff	Cova ORTHO-NERVE
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated	Biom' Up SA
510(k) Number	Not assigned	K031069	K103081
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.	Indicated for peripheral nerve injuries where there is no gap or where a 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	Porcine collagen
Dimensions	1.5 - 10 mm (diameter) x 1- 5 cm length (slit tubes) and sheets of sizes 15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm	2, 5, 7 mm (diameter) x 5 cm length (nominal)	15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm sheets
Thickness	100 µm to 1000 µm	100 µm to 1000 µm	NA
Patient population	Nerve injury, partial or complete gap	Nerve injury, complete gap	Nerve injury, partial or complete gap
Technological characteristics	Porcine tissue, ECM to remodel	Porcine tissue, ECM to remodel	Porcine tissue, ECM to remodel
Intended therapeutic effect	Protected channel for nerve healing	Protected channel for nerve healing	Protected channel for nerve healing
New issues of S/E?	No	See 510(k)	See 510(k)
Do Performance Data demonstrate equivalence?	Yes	See 510(k)	See 510(k)

Predicates of the Nerve Cuff

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.

K03/069/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)

biom'up
ADVANCED BIOMATERIALS

K103081

MAR - 2 2012

510(k) Summary

Submitter's name and address:	Biom'Up S.A. 8, Allee Irene Joliot-Curie 69800, Saint-Priest, France
Contact person:	Valerie Centis, R&D Project Manager and Regulatory Affairs Biom'Up S.A.S 8, Allee Irene Joliot-Curie 69800, Saint-Priest, France Phone: +33 (0)4 86 57 36 10 Fax: +33 (0)4 37 69 00 84 Email: regulatory.affairs@biomup.com
Date Summary was prepared:	March 2nd, 2012
Trade/Proprietary Name:	Cova™ORTHO-NERVE
Classification Name:	Nerve Cuff
Product Code:	JXI
Regulation Number:	21 CFR 882.5275
Device Classification:	Class II
Predicate Devices	Collagen Nerve Wrap (K060952) NeuraWrap™ (K041620) NeuroGen™ (K011168)

Device Description

Cova™ORTHO-NERVE is a pure collagen membrane designed to be used as a barrier to allow guided healing along distinct anatomical planes. It is completely resorbable within a time frame that is compatible with healing. The membrane is obtained by standardized, controlled manufacturing processes. Cova™ORTHO-NERVE is further sterilized in double-pouches by gamma-irradiation.

Cova™ORTHO-NERVE membranes are designed to be resorbable, non inflammatory and biocompatible for uses to treat peripheral nerve injuries. When wetted, the membrane is conformable, elastic and easy to handle. It can be used alone or, if needed, it can be

sutured in place. Cova™ORTHO-NERVE is provided in rectangular sheets of 15 x 25 mm, 20 x 30 mm, 30 x 40 mm and 40 x 60 mm. Furthermore, the device can be easily trimmed or shaped to the appropriate size, without tearing or fragmenting, to fit the zone to be treated.

Intended Use

Cova™ORTHO-NERVE is indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure can be achieved by flexion of the extremity.

Basis for Substantial Equivalence

The intended use, product design, composition, physical structure and target population of Cova™ORTHO-NERVE resorbable collagen membranes are substantially equivalent to the FDA cleared and legally marketed predicate devices Collagen Nerve Wrap (K060952), NeuraWrap™ (K041620) and NeuroGen™ (K011168). Similarities are presented in Table 1.

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ADVANCED BIOMATERIALS

Table 1. Comparison of Cova™ORTHO-NERVE with the predicate devices

Medical Device	Cova™ ORTHO-NERVE	Collagen Nerve Wrap	NeuraWrap™ Nerve Protector	NeuroGen™ Nerve Guide
510(k) Class	K103081 (tbd) JXI	K060952 JXI	K041620 JXI	K011168 JXI
Composition Origin	Type I Collagen Porcine	Type I collagen Bovine	Type I collagen Bovine	Type I collagen Bovine
Intended use	Indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure can be achieved by flexion of the extremity.	Indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue and where gap closure can be achieved by flexion of the extremity.	Indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.	Indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.
Characteristics	Membrane, rollable if needed Easy to manipulate Flexible Smooth Wettable Hemostatic Cell-occlusive	Pre-rolled membrane Easy to manipulate Flexible Smooth Wettable Hemostatic Cell-occlusive	Pre-rolled membrane Easy to manipulate Flexible Smooth Wettable Hemostatic Cell-occlusive	Tubular Easy to manipulate Flexible Smooth Wettable Hemostatic Cell-occlusive
Biocompatibility Non-pyrogenic Resorbable Suturable Sterilization	Established Yes Yes Yes Gamma irradiation	Established Yes Yes Yes Gamma irradiation	Established Yes Yes Yes Ethylene Oxide (EtO)	Established Yes Yes Yes Ethylene Oxide (EtO)
Reusable Shelf-life	Single-use 24 months	Single-use 36 months	Single-use 36 months	Single-use 36 months
Packaging	Double-peel packages	Double-peel packages	Double-peel packages	Double-peel packages

12-14

Any differences in technological characteristics between the Cova™ORTHO-NERVE and the predicate devices do not raise any new issues of safety or efficacy. The performance and safety of the material used was evaluated. The collective results have demonstrated that the Cova™ORTHO-NERVE is substantially equivalent to the respective predicate devices with regard to safety and efficacy.

Summary of Non-Clinical Data

Biocompatibility

Biocompatibility tests were selected in accordance with ISO-10993 – 1 (Biological Evaluation of Medical Devices) guidelines for a permanent implant in contact with tissue/bone. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. The table 2 provides a summary of the biocompatibility test results and conclusions.

Table 2: Biocompatibility Testing Summary for Cova™ORTHO-NERVE

Test	Test Method	Results
Cytotoxicity	ISO Direct contact Cytotoxicity Assay	Non-cytotoxic
Sensitization	ISO Guinea pig Maximization Test with device extracts (saline and sesame oil extracts)	No evidence of sensitization
Acute Intracutaneous Reactivity	ISO Acute Intracutaneous Reactivity Test in rabbits with device extracts (saline and sesame oil extracts)	No evidence of irritation
Acute Systemic Toxicity	ISO Acute Systemic Toxicity in Mice with device extracts (saline and sesame oil extracts)	No mortality or evidence of systemic toxicity
Rabbit Pyrogen Study	USP Material-mediated Rabbit Pyrogen Test with saline extract of the device	No evidence of material-mediated pyrogenicity
Hemolysis	Hemolysis Test by direct contact with human red blood cells	No hemolytic activity
Genotoxicity	ISO Ames Mutagenicity Assay with device extracts (saline and ethanol extracts)	No evidence of mutagenicity
Genotoxicity	ISO Mouse bone marrow micronucleus with device extracts (saline and sesame oil extracts)	No evidence of clastogenicity

Implantation/Absorption	Subcutaneous implantation in rats	Absorption of material by 13 weeks No inflammation observed
Implantation (safety and performance)	*In vivo* safety and performance study in rats after 3, 30 and 90 days	Protection during nerve repair No fibrous peri-nervous tissue was observed after 3, 60 or 90 days.
Subchronic / chronic toxicity	13-Week systemic toxicity and local Tolerance Study in rats following subcutaneous implantation	No adverse tissue reaction to the implant up to 13 weeks of implantation No systemic toxicity

Viral Inactivation Study

Viral Inactivation steps were validated for collagen extracted from tissues used in the manufacture of the membranes. For the validation, different viruses were selected according to their physico-chemical resistance and representativeness. The viral inactivation steps are routinely performed in process using appropriate treatment. It was demonstrated that the inactivation steps reduced down the final viral load to the limit of detection.

Bench Test

In vitro bench tests were conducted on final product to demonstrate the safety and effectiveness of the device, and to demonstrate that the device performs as it is intended. The following tests were performed and were found to meet the similar specifications as a predicate.

- Color, odor, feel Inspection
- Dimensional Inspection
- Edge Verification
- Suture strength Verification
- Tensile strength Verification
- pH Verification
- UV Spectra Verification to determine the purity of the raw material
- Enzymatic Degradation Verification
- Swelling Rate Verification
- Compression and Kinking

Moreover, Endotoxin (Limulus Amebocyte Lysate Test) testing is routinely performed on the final device to conform to the endotoxin limit of 20 EU/device.

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Animal Study

An animal study was conducted in rat model to evaluate the performance and safety (local tissue effects) of the Cova™ORTHO-NERVE membrane after nerve section and direct suture in the rat peroneal nerve. No fibrous peri-nervous tissue was observed after 3, 60 or 90 days. The membrane also demonstrated its ability to confer a protective environment for the repaired nerve. Time for re-intervention was also lowered.

Conclusion

Cova™ORTHO-NERVE Resorbable Collagen Membrane is substantially equivalent to its predicate devices: Collagen Nerve Wrap, NeuraWrap™ and NeuroGen™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Biom'up Sas
c/o Valerie Centis, Ph.D.
R&D Project Manager and Regulatory Affairs
8, Allee Irene Joliot-Curie
St-Priest, France 69800

MAR - 2 2012

Re: K103081
Trade/Device Name: Cova™ ORTHO-NERVE
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: December 21, 2011
Received: December 22, 2011

Dear Dr. Centis:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103081

Device Name: Cova™ORTHO-NERVE

Indications for Use:

Indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure can be achieved by flexion of the extremity.

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)

C G

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K103081

13. Proposed Labeling

Nerve Cuff

Manufactured by:
Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, Indiana 47906 U.S.A.
Phone: (765) 497-3355
Toll Free: (888) 299-4224
Fax: (765) 497-2361

EC Representative:
Cook Ireland
O'Halloran Road
National Technological Park
Limerick, IRELAND
Phone: +353 61 334440

DESCRIPTION

The Nerve Cuff is an implant that provides non-constricting protection for peripheral nerves. Nerve Cuff is designed to be an interface between the nerve and the surrounding tissue. Nerve Cuff is an extracellular matrix (ECM) that is either a tube with a slit or a flat sheet, and is fully remodeled during the healing process. When hydrated, Nerve Cuff is easy to handle, soft, pliable, nonfriable, and porous. Nerve Cuff is flexible to accommodate movement of the joint and associated tendons, and has sufficient mechanical strength to hold sutures. Nerve Cuff is provided sterile, for single use only, and in a variety of sizes to meet the surgeon's needs.

INDICATIONS FOR USE

The Nerve Cuff is indicated for 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 is intended for one-time use.

Rx ONLY This symbol means the following:

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
This product is intended for use by trained medical professionals.

CONTRAINDICATIONS

The Nerve Cuff is derived from a porcine source and should not be used for patients with known sensitivity to porcine material.
NOTE: This device not intended for use in vascular applications.

COMPOSITION

Nerve Cuff is an extracellular membrane derived from the Small Intestinal Submucosa (SIS) of pigs from qualified animal production facilities. SIS is obtained from the intestine using a process that retains the natural composition of matrix molecules such as collagen (Types I, III, VI), glycosaminoglycans (hyaluronic acid, chondroitin sulfate A and B, heparin, and heparan sulfate), proteoglycans, growth factors (FGF-2, TGF-β), and fibronectin.[1 2 3]

PROPERTIES

Nerve Cuff adapts to the dimensions of the surgical site once hydrated. After hydration in the site, the material remains in place and is not disrupted by the closure of the surgical site. If desired, Nerve Cuff can be fixated with a suture.

SAFETY

A viral inactivation study using the Nerve Cuff material demonstrated at least a 6.1-log reduction of the PrV virus, a 5.5-log reduction in Reo-3, 4.3-log reduction in A-MuLV and 3.6 log in PPV. This represented a reduction in viral burden to the level of detection in the test. Data were published in the peer reviewed article cited in the references.[4]

PRECAUTIONS

- This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.
- **Do not resterilize device.**
- Discard all open and unused portions of device.
- Device is sterile provided the package is dry, unopened and undamaged. Do not use device if the package seal is damaged or open.
- Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Do not suture device prior to rehydration.

POTENTIAL COMPLICATIONS

Possible complications can occur with any nerve repair surgical procedure including pain, infection, decreased or increased nerve sensitivity, and complications associated with use of anesthesia. If any of the following conditions occur and cannot be resolved, careful removal of the device should be considered:

- Infection
- Allergic reaction
- Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation)

STORAGE

The Nerve Cuff should be stored in a clean, dry location at room temperature.

STERILIZATION

This device has been sterilized with ethylene oxide.

USE OF ANTIMICROBIALS

Because the device is at times used in surgical fields where sterility cannot be assured, the use of antimicrobials is common practice and may prevent infectious complications.[1] In these cases both antibiotic prophylaxis of the patient and antimicrobial soaking of the cylinder have been used. Typical flora can be expected to include a variety of aerobic and facultative anaerobic organisms, including, but not limited to, *Staphylococcus aureus, Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, and *Escherichia coli*. Therefore the following points should be considered:

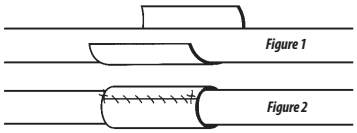
- Antimicrobials, if used topically or systemically, should provide coverage against a wide spectrum of aerobic and anaerobic organisms.[2]
- Antibacterial prophylaxis, if chosen, should be started prior to surgery and continued postoperatively.[1]

The presence of certain antimicrobials may inhibit revascularization and/or infiltration of cells into the cylinder.[3 5] For example, gentamicin is known to hinder neovascularization, epithelialization, and keratinocyte growth,[4] while povidone iodine,[6] bacitracin,[3 6] polymyxin B,[7] and vancomycin[8] have all been reported to slow or inhibit wound healing. However, no studies have been conducted to evaluate the combination of antimicrobials with the cylinder.

SUGGESTED INSTRUCTIONS FOR USE

NOTE: These recommendations are designed to serve only as a general procedure. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. Always handle Nerve Cuff using aseptic technique. Minimize contact with latex gloves.

1. Follow standard operating procedures for exposure and mobilization of the nerve. Determine the nerve diameter in millimeters (mm) using a suitable measuring instrument. If necessary, repair the nerve using standard operating procedures. Select an Nerve Cuff of sufficient diameter to account for normal edema following traumatic nerve injury. The Nerve Cuff diameter should be at least 1-2mm larger than the measured nerve diameter and long enough to cover the affected area.
2. Open the outer carton and remove the sterile pouch. Using standard aseptic technique, open the pouch and pass the inner tray to the sterile field for further handling.
3. Open the tray, and, if necessary trim the Nerve Cuff to the appropriate dimensions for covering the damaged portion of the nerve. The Nerve Cuff may be trimmed after hydration if desired.
4. Fill the pre-molded rehydration reservoir with room temperature sterile saline or sterile Lactated Ringer's solution. Hydrate the Nerve Cuff for 10 seconds or until the desired handling characteristics are achieved.
5. Position the Nerve Cuff around the nerve (Figure 1). If desired, gently flush the device with sterile saline or Lactated Ringer's solution to improve conformability with the nerve. Secure the device as necessary. This may include placing running sutures along the longitudinal slit to enclose the nerve, and/or stay sutures through the nerve epineurium. See Figure 2 for completed repair.



6. Discard any unused portions of the Nerve Cuff according to institutional guidelines for biological waste. Do not resterilize.

HOW SUPPLIED

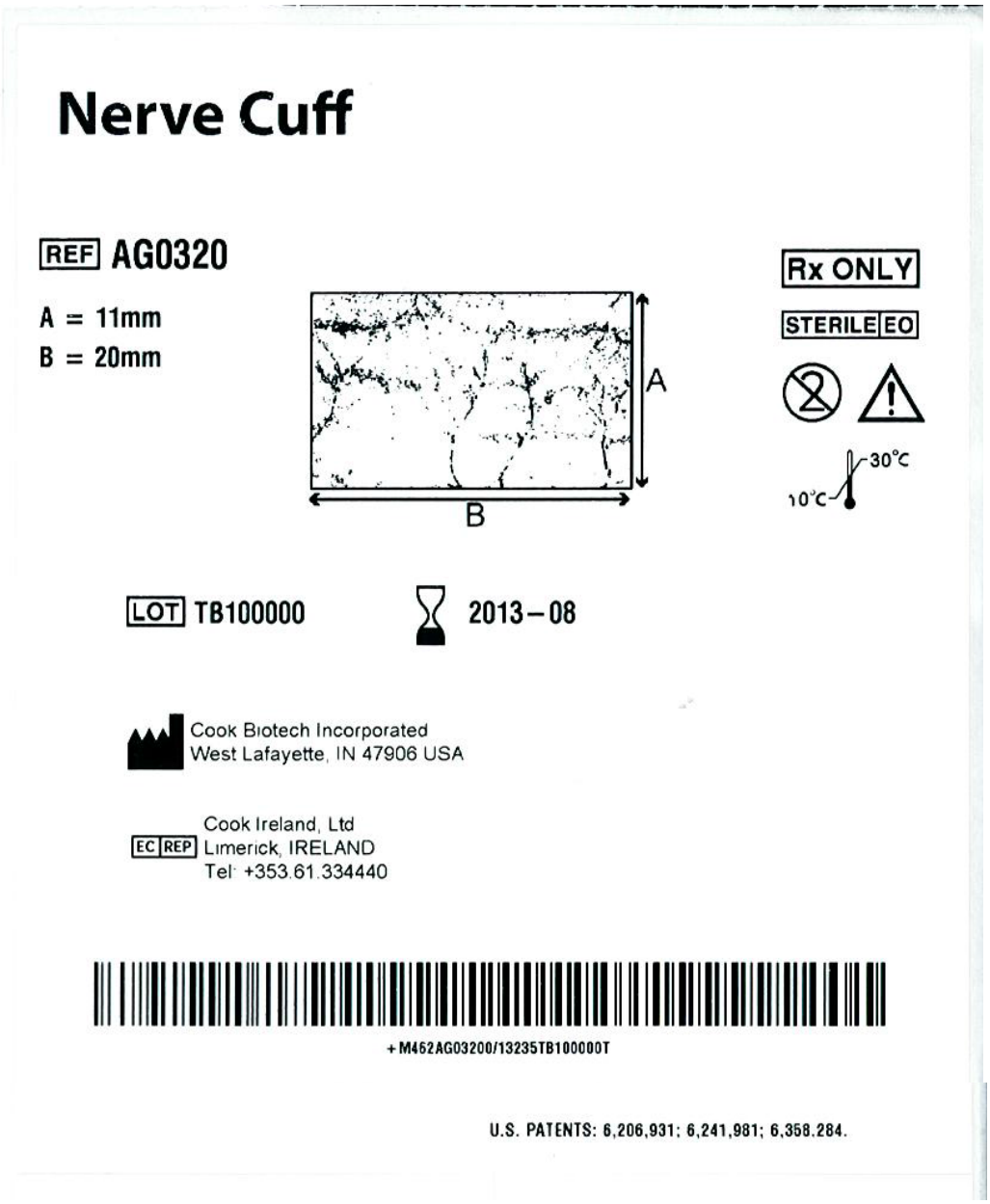
Nerve Cuff is placed into a plastic tray (for the slit tube) and then inserted into a sterile pouch. The flat sheet configuration is placed in a inner pouch within the sterile outer pouch. The pouch is heat-sealed to provide a sterile barrier and has a peelable seal. Contents of the package are guaranteed sterile unless the package is opened or damaged. The Nerve Cuff and packaging do not contain natural rubber latex. *Do not use Nerve Cuff if the peelable pouch appears to be open or damaged.*

REFERENCES

1. Mangram, A., et al, *Guideline for prevention of surgical site infection, 1999*. Centers for Disease Control and Prevention (CDC). 1999.
2. Aldridge, K.E., et al., *Multicenter survey of the changing in vitro antimicrobial susceptibilities of clinical isolates of Bacteroides fragilis group, Prevotella, Fusobacterium, Porphyromonas, and Peptostreptococcus species*. Antimicrob Agents Chemother, 2001. 45(4): p. 1238-43.
3. Petroutsos, G., et al., *Antibiotics and corneal epithelial wound healing*. Arch Ophthalmol, 1983. 101(11): p. 1775-8.
4. Bang, K., et al., *Gentacoll hampers epithelialisation and neovascularisation in excisional wounds in hairless mice*. Scand J Plast Reconstr Surg Hand Surg, 1998. 32(2): p. 129-33.
5. Nelson, J.D., et al., *Corneal epithelial wound healing: a tissue culture assay on the effect of antibiotics*. Curr Eye Res, 1990. 9(3): p. 277-85.
6. Kjolseth, D., et al., *Comparison of the effects of commonly used wound agents on epithelialization and neovascularization*. J Am Coll Surg, 1994. 179(3): p. 305-12.
7. Nakamura, M., et al., *Effects of antimicrobials on corneal epithelial migration*. Curr Eye Res, 1993. 12(8): p. 733-40.
8. Petroutsos, G., et al., *The effect of concentrated antibiotics on the rabbit's corneal epithelium*. Int Ophthalmol, 1984. 7(2): p. 65-9.

MANUFACTURER
TEMPERATURE LIMITATION
USE BY
DO NOT REUSE
ATTENTION, SEE INSTRUCTIONS FOR USE
KEEP DRY
STERILE EO STERILIZED USING ETHYLENE OXIDE

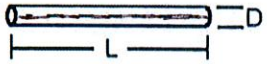
Draft Outer Labels of the Nerve Cuff



Nerve Cuff

REF AG0220

D = 2mm
L = 20mm



Rx ONLY

STERILE EO

LOT TB100000

2013–08

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EC REP Cook Ireland, Ltd
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Tel: +353.61.334440

+M462AG02200/13235TB100000S

U.S. PATENTS: 6,206,931; 6,241,981; 6,358,284.

14. Sterilization

Sterilization

Sterilization

The Nerve Cuff will be sterilized using an established ethylene oxide (EO) sterilization cycle that has been validated to a sterility assurance level (SAL) of 10^{-6} in conformance with EN 11135- 2007: *Sterilization of Health Care Products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*. Using the exhaustive extraction technique, the EO sterilization residuals have been verified to be less than the maximum allowable limits (4 mg for ethylene oxide and 9 mg for ethylene chlorohydrin) as defined by ISO 10993-7 *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*. The sterilization validation report is found in the device master file (b)(4)Trade Secret Process. The EO and ECH residuals test report is found in the pages following this section.

Packaging

The Nerve Cuff will be terminally sterilized within a tray in a pouch system using ethylene oxide as described above. The tray-pouch system allows transfer of the inner tray, which is sterile, into the sterile field. The tray is made of PETG and the outer pouch consists of an outer film with Tyvek® paper backing that forms a pouch. The flat sheet configuration of the Nerve Cuff will be placed within a double Tyvek® pouch. After packaging, the Nerve Cuff will be transported for sterilization and labeled. Please see Section 13 – *Proposed Labeling* for an image of the Draft Outer Package Label for the device.

Shelf-Life

The shelf-life of the Nerve Cuff is identical to that of its predicate Surgisis Nerve Cuff (K031069) which is labeled at 18 months. Shelf life testing for finished SIS devices is described in the device master file MAF-1036, Series 1000, Section 1032. Results of the testing provide reasonable assurance that the Nerve Cuff will maintain sterility and performance characteristics following at least 18 months of storage.

(b)(4)Trade Secret Process -Testing Report

(b)(4)Trade Secret Process -Testing Report

(b)(4)Trade Secret Process -Testing Report

(b)(4)Trade Secret Process -Testing Report

(b)(4)Trade Secret Process -Testing Report

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(b)(4)Trade Secret Process -Testing Report

(b)(4)Trade Secret Process -Testing Report

(b)(4)Trade Secret Process -Testing Report

15. Biocompatibility

Biocompatibility

Biocompatibility of the Nerve Cuff has been demonstrated by conducting a full range of testing in conformance with ISO 10993 - *Biological evaluation of medical devices*, using terminally sterilized SIS, which is the same material used for the Nerve Cuff. Please refer to Table 15-1 for a summary of test results as well as the location of the test reports in the Device Master File.

Table 15-1: Biocompatibility Test Results

Test	ISO 10993 Part	Result	Reference
Genotoxicity	3	Pass	(b)(4)Trade Secret Process - Testing Report [redacted]
Direct Contact In Vitro Hemolysis	4	Pass	[redacted]
Cytotoxicity	5	Pass	[redacted]
Muscle Implantation	6	Pass	[redacted]
Acute Intracutaneous Reactivity	10	Pass	[redacted]
ISO Sensitization	10	Pass	[redacted]
Acute Systemic Toxicity	11	Pass	[redacted]
Pyrogenicity	11	Pass	[redacted]
LAL Endotoxins	11	Pass	[redacted]
Subchronic Systemic Toxicity	11	Pass	[redacted]

Based on the results of this testing, it was concluded that the Nerve Cuff is biocompatible as a permanent (> 30 days) tissue/bone implant device. A Letter Granting Access to the relevant sections of the Master File is included in Section 11 – *Device Description*.

16. Software

(Not Applicable)

17. Electromagnetic Compatibility and Electrical Safety

(Not Applicable)

18. Performance Testing - Bench

Performance Testing – Bench

Mechanical Testing

The SIS material, which comprises the predicate Surgisis Nerve Cuff, as well as the Nerve Cuff (subject device), has undergone extensive testing to characterize its mechanical and physical performance in terms of suture retention strength and tensile strength. All finished device samples were rehydrated in sterile saline for at least five minutes prior to testing.

Suture Retention Strength

Suture retention strength testing was performed in accordance with the Good Laboratory Practices regulations, 21 CFR 58, using ISO 7198:1998 - *Cardiovascular Implants – Tubular Vascular Prostheses*, Section 8.8 as a guide. The report and protocol are found in the Device Master File MAF-1036, Section 4043. Briefly, the suture retention strength of 15 finished, hydrated devices from 3 different lots (5 devices per lot) was evaluated using 5-0 suture and a bite depth of two millimeters. The suture loop was pulled through the test article at a constant rate of 150 mm/min in the longitudinal direction. The resulting mean suture retention strength was (b)(4)Trade Secret Process - Testing Report. These results are from tests performed on the tubular (no slit) configuration. However, these results still apply to the current device since the material and tubular configuration are not significantly different from the predicate.

Tensile Strength

Tensile strength testing was also performed in accordance with the Good Laboratory Practices regulations, 21 CFR 58, using the following standards: ISO 1798:2008 - *Flexible Cellular Polymeric Materials – Determination of Tensile Strength and Elongation at Break*, and ISO 13934:1999 – *Textiles – Tensile properties of fabrics – Part 1: Determination of Maximum Force and Elongation at Maximum Force Using the Strip Method*. The detailed report and protocol can be found in the device master file (b)(4)Trade Secret Process Testing Report Briefly, testing was performed using 15 finished samples from 3 lots (5 samples per lot). These samples were pulled at a fixed rate until failure. Results show an average ultimate tensile strength of (b)(4)Trade Secret Process These results are from tests performed on the tubular (no slit) configuration. However, these results still apply to the current device since the material and tubular configuration are not significantly different from the predicate.

Thus, the results of the mechanical strength tests show that the Nerve Cuff is adequate for this application.

19. Performance Testing - Animal

Performance Testing – Animal

The SIS material comprising the Nerve Cuff was evaluated as a nerve wrap in an animal study. The abstract of the article is written below and the article is found in the following pages in this section.

(b)(4)Trade Secret Process -Article

[redacted]

(b)(4)Trade Secret Process -Article

[redacted]

(b)(4)Trade Secret Process -Article

(b)(4)Trade Secret Process -Article

(b)(4)Trade Secret Process -Article

(b)(4)Trade Secret Process -Article

(b)(4)Trade Secret Process -Article

(b)(4)Trade Secret Process -Article

(b)(4)Trade Secret Process -Article

(b)(4)Trade Secret Process -Article

(b)(4)Trade Secret Process -Article

(b)(4)Trade Secret Process -Article

20. Performance Testing – Clinical Experience
(Not applicable)

21. Clinical Trials Certification
(Not applicable)

22. Other – RTA Checklist

This checklist is copied from the guidance document "Refuse to Accept Policy for 510(k)s (Issued December 31, 2012)." CBI is providing this checklist to help the reviewer identify and locate the required components within the submission. The checklist is only meant to be a guide. CBI has not modified the contents of the checklist except for underlined sections clearly marked as "CBI comments." The comments are provided to explain CBI's position as to why CBI believes CBI has adequately addressed each item for the purposes of the refuse to accept policy. CBI understands that the "refuse to accept" review is only an administrative review, not a substantive review, and that an acceptance for review does not guarantee or suggest in any way that the device is or will be cleared.

Acceptance Checklist - For Traditional 510(k)s

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	☐	☐
Cook Biotech (CBI) comments: The subject of this submission is a device.		

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	☒	☐
CBI comments: The subject 510(k) is submitted to the Center for Devices and Radiological Health.		
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, skip this question.	☐ ☐	☐ ☐

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
CBI comments: A RFD was not submitted for the device.		
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐
CBI comments: This device is a Class II device and is eligible for a 510(k) submission. Its predicate is a 510(k) cleared device.		
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.	☐	☒
CBI comments: CBI is not aware of any pending PMA for the same device with the same indications for use.		
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.	☐	☐
CBI Comments: No clinical studies are submitted.		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.

If the answer to 3a or 3b appears to be "No," then stop the review and contact the

CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.

If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 6 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation*		
	Yes	No
a. Submission contains Table of Contents	☒	☐
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	☒	☐
Cook Biotech Incorporated (CBI) Comments: All items listed above are included in the submission.		

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	·Any "No" answer will result in a "Refuse to Accept" decision.			

	·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		☒		☐
		CBI Comment: All content used to support this submission is written in English.				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):		☒		☐
		a.	Device trade name or proprietary name	☒		☐
		b.	Device common name	☒		☐
		c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☒		☐
		CBI Comment: The device trade name/proprietary name, common name and device classification can be found in both the Cover Letter (Section3) and in the 510(k) Summary (Section 5).				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request*		☒		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		the correct format during substantive review.				
		CBI Comment: The Indications for Use Statement can be found in Section 4 of this submission.				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) in Comments.*		☒		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	☒	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93	☐	☒	☐
		CBI Comment: The 510(k) Summary can be found in section 5 of this submission.				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. Select "Yes" if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*		☒		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
		·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
		CBI Comment: The Truthful and Accuracy Statement can be found in section 6 of this submission.			
	6.	Submission contains Class III Summary and Certification *See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).*	☐	☒	☐
		CBI Comment: The Class III Summary and Certification does not apply for this device.			
	7.	Submission contains clinical data *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.*	☐	☒	
		a. Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a*	☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			"covered clinical study" as defined in the Guidance for Industry- Financial Disclosures by ClinicalInvestigators			
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec.801(j)*	☐	☐	☐
		CBI Comment: No clinical studies are submitted, hence the relevant FDA Forms are not applicable for this submission.				
	8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654) *There should be a completed form for each referenced national or international standard.*		☒	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
		Select "N/A" only if submission does not reference any standards.			
		CBI Comment: The completed Standards Data Report for 510(k)s (Form 3654) can be found in section 9, Declarations of Conformity and Summary Reports.			
	9.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre- Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no*	☒		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		prior submissions.				
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review.* For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the Agency's current thinking on this topic.	☒	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			Select "N/A" if the submitter states there were no prior submissions in criterion above.			
		CBI Comment: The subject device has not been submitted previously. However, the CBI predicate devices' 510(k) is listed in the CDRH Premarket Review Cover Sheet since they are made from the same base material, and the predicate has been cleared by FDA for its intended use.				
B.	**Device Description**					
	10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive*	☒	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			review.			
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☒	☐
		CBI Comment: Device description can be found in Section 11, Device Description, of this submission.				
	11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent				

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	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	☒		☐
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒		☐
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	☒	☐	☐
		CBI Comment: Section 11, Device Description, includes Mode of Operation of the subject device; additional information on the device use is found in Section 13, Proposed Labeling, that contains the Draft Instructions for Use.				
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are		☒	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	clear, legible, labeled, and include dimensions. *In lieu of drawings, schematics, etc. of each device to be* *marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.* *Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*			
	CBI Comment: Representative images are included in the Section 11, Device Description of this submission.			
13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*		☒	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☐	☒	☐
		b.	Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☒	☐
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.*	☐	☒	☐
		CBI Comment: The subject device does not have multiple components and is a single device.				

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	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
C.	**Substantial Equivalence Discussion**					
	14.	Submitter has identified a predicate(s) device		☐		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm).*	☒		☐
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☒		☐
		CBI Comment: Predicate 510(k) information can be found in Section 12,				

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	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		Substantial Equivalence Discussion.				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	☒		☐
		b.	Technology, including features, materials, and principles of operation	☒		☐
		CBI Comment: Comparison of Indications for use and technology can be found in Section 12 Substantial Equivalence Information and in Table 12-1, as well as in the 510(k) Summary (Section 5).				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act		☒	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	and 21 CFR 807.87(f)) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed*			
	CBI Comment: Analysis of differences can be found in Section 12, Substantial Equivalence Discussion.			
D.	**Proposed Labeling (see also 21 CFR part 801)** *If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if "N/A"*		☐	

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	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	is selected. IVD labeling is addressed in section 21 below.					
	17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use		☒		☐
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☒		☐
		b.	Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒		☐
		CBI Comment: Proposed labeling and Draft Instructions for Use can be found in Section 13, Proposed Labeling.				

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	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*		☐	☒	☐
		CBI Comment: The device is intended to be for prescription use only.				
	19.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	☒		☐
		b.	Labeling includes device common or usual name (21 CFR 801.61) *Select "N/A" if device is for prescription use only.*	☒	☐	☐
		CBI Comment: The labeling includes the name and place of business of the manufacture and also includes the device common name.				
	20.	a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling	☒	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*			
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during*	☐	☒	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			the substantive review.			
		c.	If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☒	☐
		CBI Comment: CBI follows and is compliant with general labeling guidances for its devices.				

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	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	21. If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*	☐	☒	☐
	CBI Comment: The device is not an in vitro diagnostic device.			
E.	**Sterilization** *If in vitro diagnostic (IVD) device and sterilization is not applicable, select* *"N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.* Submission states that the device and/or accessories are: (*one of the below must be checked*) ☒ provided sterile ☐ provided non-sterile but sterilized by the end user non-sterile when used This information will determine whether and what type of		☐	

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	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.* *If information regarding the sterility status of the device is not provided, select "No."*					
	<u>CBI Comment: The entire device is provided sterile</u>					
	22.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	☒	☐	☐
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	☐	☒	☐
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☐	☒	☐
		<u>CBI Comment: Assessment of the need for sterilization information can be</u>				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
		·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
		<u>found in Section 14, Sterilization. The entire device is provided sterile and is not to be reused or resterilized.</u>			
	23.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.*		☐	
		a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☒		☐
		b. A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	☒		☐
		c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	☒	☐	☐

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	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			Select "N/A" if not sterilized using chemical sterilants			
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☒		☐
		e.	Sterility Assurance Level (SAL) stated	☒		☐
		CBI comment: Sterilization method, validation method, maximum levels of residual sterilant, description of packaging and sterility assurance levels can be found in Section 14, Sterilization.				
	24.	If the device, and/or accessory, and/or a component is end user sterilized: *Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.*			☒	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation is not required.*	☐		☐
		c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☐		☐
		d.	Submission includes sterilization instructions for end user	☐		☐
		CBI comment: The device is not end user sterilized.				
	25.	a.	If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note*	☒	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
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			that the adequacy of how such requirements have been addressed should be assessed during the substantive review.			
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☒	☐	☐
		c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special	☒	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*			
		CBI Comment: ISO 10993 standards were followed as well as the FDA Guidance "Use of ISO 10993: Biological Evaluation of Medica Devices" in the sterilization of the subject device.				
F.	**Shelf Life**					

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
	26.	Proposed shelf life/expiration date stated *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*	☒	☐	☐
		CBI comment: Proposed shelf life/expiration date is 18 months. This information can be found in Section 14 Sterilization.			
	27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. *Select "N/A" if the device is not provided sterile.*	☒	☐	☐
		CBI comment: Summary of methods used to establish sterility can be found in Section 14, Sterilization.			
	28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for	☒		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	why the storage conditions are not expected to affect device safety or effectiveness.			
	CBI comment: Summary of methods used to establish device performance is not adversely affected by aging can be found in Section 14 Sterilization.			
G.	Biocompatibility *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.* Submission states that there: (*one of the below must be checked*) ☒ are ☐ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial		☐	

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
	equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*				
	29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	☒		☐
		CBI comment: The subject device is a single item. However, it is patient contacting. The 510(k) lists device composition and references the Device Master File on the composition of the material comprising the device.			
	30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☒		☐
		CBI comment: Contact classification can be found in Section 15, Biocompatibility			

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	31. Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☒		☐
	CBI comment: Biocompatibility assessment of subject can be found in Section 15, Biocompatibility			
H.	**Software**			
	Submission states that the device: (*one of the below must be checked*) ☐ does ☒ does not			☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*			
	CBI comment: This device does not contain software.			
	32. Submission includes a statement of software level of concern and rationale for the software level of concern	☐		☐
	CBI comment: This device does not contain software.			
	33. All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	identified an alternate approach with a rationale).			
	CBI comment: This device does not contain software.			
I.	**EMC and Electrical Safety**			
	Submission states that the device: (*one of the below must be checked*) ☐ does ☒ does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*			☐
	CBI comment: This device does not require EMC and electrical safety evaluation.			

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	34. Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐		☐
	<u>CBI comment: This device does not require EMC and electrical safety evaluation</u>			
	35. Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation	☐		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
		·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
		using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).			
		CBI comment: This device does not require EMC and electrical safety evaluation			
J.	**Performance Data – General** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.*			☐	
	36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an	☒	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		explanation of how the data generated from the test supports a finding of substantial equivalence. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*				
		CBI comment: A full test report is provided for each completed test. In relevant sections where the report is in the Master File, the section of the Master File is referenced instead, and a Letter Granting Access to the Master File is found in Section 11, Device Description.				
	37.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have*	☒	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			been addressed should be assessed during the substantive review.			
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☒	☒	☐
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation	☒	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*			
		CBI comment: CBI has conducted all relevant performance characteristics testing relevant to Standards referenced in Section 9, Declaration of Conformity and Summary Reports. The data show that the subject device meets safety and effectiveness measures for its application.				
	38.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a*			☐	

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		discussion is required to support acceptance.				
		a.	Legible reprints or a summary of each article	☒		☐
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☒		☐
		CBI comment: The submission contains a legible reprint of the article supporting substantial equivalence with discussion on its applicability supporting SE.				
	39.	For each completed nonclinical (i.e., animal) study conducted, *Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,*		☒	☐	☐
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☒		☐
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☒		☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐		☒
		CBI comment: The referenced animal study was performed as described in the peer-reviewed article included in this submission. It is not known whether the study was performed under GLP conditions. However, CBI believes that the protocols and data in the article has been subject to rigorous (peer) review which should satisfy GLP requirements.				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**					
	Submission indicates that device: (*one of the below must be checked*) ☐ is ☒ is not					

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	CBI comment: This device is not an in vitro diagnostic device (IVD).					
	40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:		☐	☐	☐
		a.	Precision/reproducibility	☐	☐	☐
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☐	☐
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐
		d.	Analytical specificity			

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		CBI comment: This device is not an in vitro diagnostic device (IVD).				
	41.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device- specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific*	☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special*	☐	☐	☐

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission will be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	·Any "No" answer will result in a "Refuse to Accept" decision. ·Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			controls document have been addressed should be assessed during the substantive review.			
		CBI comment: This device is not an in vitro diagnostic device (IVD).				

K132660/S001

COOK BIOTECH INCORPORATED
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906-1000 U.S.A.
PHONE: 765.497.3355 TOLL FREE: 888.299.4224
WWW.COOKBIOTECH.COM

September 12, 2013

FDA CDRH DMC
SEP 13 2013
Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Device: **Nerve Cuff (K132660)**
This Submission: **Response to RTA**

Dear Sir/Madam,

Please receive enclosed the response to the RTA Hold for the Nerve Cuff (K132660).

Two copies of this 510(k) Premarket Notification are included, one in electronic form. **The electronic copy (eCopy) is the exact duplicate of the paper submission.**

The intent of Cook Biotech Incorporated to market this device is confidential commercial information. We request that it be considered as such by the FDA and not be available through Freedom of Information except where required by law. Cook Biotech Incorporated requests that the contents of the premarket notification submission be considered as company confidential for an indefinite time period. Unless prior permission from Cook Biotech Incorporated has been obtained, release to the public of any information that has been noted as company confidential will be considered a violation of company rights.

If you should have any questions concerning this premarket notification, please call me at (765) 497-3355 or email me at pguinn@cookbiotech.com.

Sincerely,

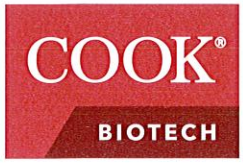
Perry W. Guinn

Perry W. Guinn

Vice President, Regulatory Affairs and Quality Assurance

PWG:maf

Enclosures



COOK BIOTECH INCORPORATED
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WWW.COOKBIOTECH.COM

September 12, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Device: **Nerve Cuff (K132660)**
This Submission: **Response to RTA**

Dear Sir/Madam,

Please receive enclosed the response to the RTA Hold for the Nerve Cuff (K132660).

Two copies of this 510(k) Premarket Notification are included, one in electronic form. **The electronic copy (eCopy) is the exact duplicate of the paper submission.**

The intent of Cook Biotech Incorporated to market this device is confidential commercial information. We request that it be considered as such by the FDA and not be available through Freedom of Information except where required by law. Cook Biotech Incorporated requests that the contents of the premarket notification submission be considered as company confidential for an indefinite time period. Unless prior permission from Cook Biotech Incorporated has been obtained, release to the public of any information that has been noted as company confidential will be considered a violation of company rights.

If you should have any questions concerning this premarket notification, please call me at (765) 497-3355 or email me at pguinn@cookbiotech.com.

Sincerely,

Perry W. Guinn

Vice President, Regulatory Affairs and Quality Assurance

PWG:maf

Enclosures

A. Administrative

(b)(4)Trade Secret Process

[redacted]

Question 5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k).

FDA Comment: The statement references the wrong regulation. The correct regulation should be 21 CFR 807.87(k).

CBI Response:

A Truthful and Accuracy Statement that references the correct regulation (21 CFR 807.87(k)) is found in **Appendix B** of this Response.

(b)(4)Trade Secret Process

[redacted]

Appendix A

Revised 510(k) Summary

510(k) Summary

September 12, 2013

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 and similar to its other predicate, Cova ORTHO-NERVE (K103081) manufactured by Biom' Up S.A (France). 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 predicates Surgisis Nerve Cuff and Cova ORTHO-

NERVE, as shown through bench and animal studies, biocompatibility testing and clinical studies:

Bench testing:

- Ultimate tensile strength
- Suture retention strength

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

Biocompatibility testing:

- Genotoxicity
- Direct contact *in vitro* hemolysis
- Cytotoxicity
- Muscle implantation
- Acute intracutaneous reactivity
- Sensitization
- Acute systemic toxicity
- Pyrogenicity
- LAL endotoxins
- Subchronic 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 devices in terms of safety and effectiveness as shown in bench and animal studies.

Table of Substantial Equivalence

Device	**Nerve Cuff**	**Surgisis Nerve Cuff**	**Cova ORTHO-NERVE**
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated	Biom' Up SA
510(k) Number	K131015	K031069	K103081
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.	Indicated for peripheral nerve injuries where there is no gap or where a 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	Porcine collagen
Dimensions	1.5 - 10 mm (diameter) x 1- 5 cm length (slit tubes) and sheets of sizes 15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm	2, 5, 7 mm (diameter) x 5 cm length (nominal) (tubes)	15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm sheets
Thickness	100 µm to 1000 µm	100 µm to 1000 µm	NA

Appendix B

Truthful and Accuracy Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT*
(As Required By 21 CFR 807.87(k))

I certify that, in my capacity as Vice President of Regulatory Affairs and Quality Assurance of Cook Biotech Incorporated, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Perry W. Guinn

[*Signature*]

Perry W. Guinn, VP of Regulatory Affairs and Quality Assurance
[Typed Name and Title]

Cook Biotech Incorporated 12 Sept 2013

[Company] [Date]

K131015
[*Premarket Notification (510(k)) Number*]

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)

Appendix C

Form FDA 3654 for ANSI/AAMI/ISO 22442-2

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI/ISO 22442-02 Medical Devices Utilizing Animal Tissues and their derivatives – Part 2: Control on sourcing...

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

COOK BIOTECH INCORPORATED
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906-1000 U.S.A.
PHONE: 765.497.3355 TOLL FREE: 888.299.4224
WWW.COOKBIOTECH.COM

K132660/S002

FDA CDRH DMC
DEC 09 2013
Received

December 5, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Device: **Nerve Cuff**
This Submission: **K132660/S1**

Dear Sir/Madam,

Please receive enclosed Cook Biotech Incorporated's response to FDA's questions (K132660/S1).

Two copies of this response are included, one in electronic form. **The electronic copy is the exact duplicate of the paper submission.**

The intent of Cook Biotech Incorporated to market this device is confidential commercial information. We request that it be considered as such by the FDA and not be available through Freedom of Information except where required by law. Cook Biotech Incorporated requests that the contents of this submission be considered as company confidential for an indefinite time period. Unless prior permission from Cook Biotech Incorporated has been obtained, release to the public of any information that has been noted as company confidential will be considered a violation of company rights.

If you should have any questions concerning this premarket notification, please call me at (765) 497-3355 or email me at pguinn@cookbiotech.com.

Sincerely,

Perry W. Guinn

Vice President, Regulatory Affairs and Quality Assurance

PWG:maf

Enclosures

COOK BIOTECH INCORPORATED
1425 INNOVATION PLACE
WEST LAFAYETTE, IN 47906-1000 U.S.A.
PHONE: 765.497.3355 TOLL FREE: 888.299.4224
WWW.COOKBIOTECH.COM

December 5, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Sincerely,

Perry W. Guinn

Vice President, Regulatory Affairs and Quality Assurance

PWG:maf

Enclosures

(b)(4)Trade Secret Process

[redacted]

Table 1: Physical Specification

Attribute	Value	Tolerance

(b)(4)Trade Secret Process

[redacted]

Attribute	Value	Tolerance
(b)(4)Trade Secret Process	[redacted]	

The sample book is a controlled, quality system entity which production keeps as a tangible representation of defects. CBI has sample books where actual defects of product or packaging defects are displayed for the production associate's benefit.

Table 2: Physical Specifications based on size (slit tubes)

See Figure 1 for dimension reference

NOTE: Only measurement of the items in bold are required during inspection. The [redacted] (b)(4) Trade

[redacted]	[redacted]	(b)(4) Trade Secret Process [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Company Confidential

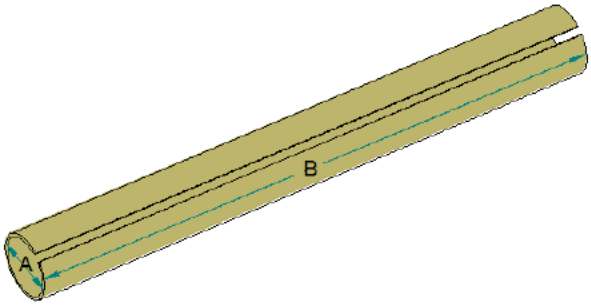

Figure 1: Slit tube Pictorial Description

Table 3: Sheet Physical Specifications

(b)(4)Trade Secret Process	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]
	[redacted]	[redacted]

Company Confidential

(b)(4)Trade Secret Process	[redacted]	[redacted]
	[redacted]	
	[redacted]	[redacted]

*See Sample Book

Table 4: Specifications Based on Size (Sheet)

[redacted]	(b)(4) Trade Secret Process	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

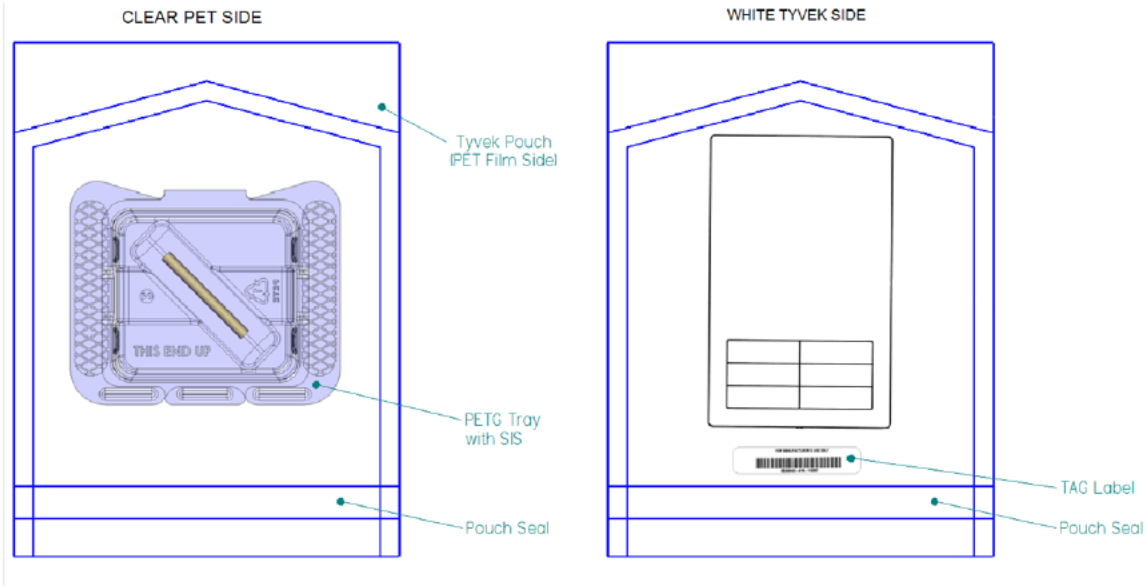

Figure 2: Packaging Scheme for Slit Tube Product

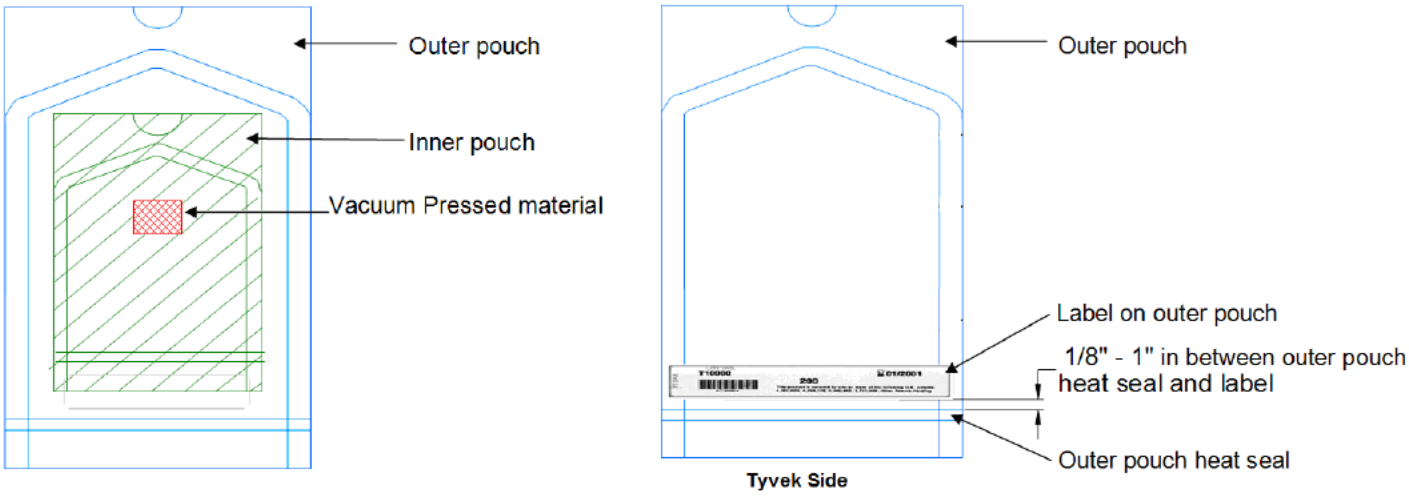

Figure 3: Packaging Scheme for Flat Sheet Product

Company Confidential

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

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(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

(b)(4)Trade Secret Process

[redacted]

Appendix A

Testing for Thickness

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

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(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

Appendix B

Compression and Rebound Test for Surgisis Nerve Cuff

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

Appendix C

Form FDA 3654

ISO 10993-7: Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO - 10993 - 7 (2008): Biological evaluation of medical devices - Ethylene oxide sterilization residuals

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-279	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Use of ISO 10993: Biological Evaluation of Medical Devices

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO - 10993 - 7: Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 7	Ethylene oxide sterilization residuals	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
4.4.6.2 Exhaustive extraction (acceptable alternative method)

DESCRIPTION
Different sizes of test articles were extracted with sterile water for 24 hrs at 37 deg C under exhaustive conditions

JUSTIFICATION
annex E Extraction condition for determination of residual ethylene oxide

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Appendix D

Packaging and Shelf-Life Testing

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

APPENDIX – PROTOCOL FOR TESTING

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

Appendix E

Draft Outer Labeling (Red-lined)

(b)(4)Trade Secret Process - Draft

(b)(4)Trade Secret Process - Draft

Appendix F

Revised 510(k) Summary

510(k) Summary

~~September 12~~December 5, 2013

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 and similar to its other predicate, Cova ORTHO-NERVE (K103081) manufactured by Biom' Up S.A (France). 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 predicates Surgisis Nerve Cuff and Cova ORTHO-

NERVE, as shown through bench~~ and~~, biocompatibility and animal studies.~~ biocompatibility testing, and clinical 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

- ~~Ultimate tensile strength~~
- ~~Suture retention strength~~

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

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Test	Results	Conclusions
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 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.	Non-irritant at 24 weeks after implantation
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 0.06 EU/ml as required by FDA for devices contacting cerebrospinal tissue.	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

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- ~~Genotoxicity~~
- ~~Direct contact *in vitro* hemolysis~~
- ~~Cytotoxicity~~
- ~~Muscle implantation~~
- ~~Acute intracutaneous reactivity~~

- ~~Sensitization~~
- ~~Acute systemic toxicity~~
- ~~Pyrogenicity~~
- ~~LAL endotoxins~~
- ~~Subchronic 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 devices in terms of safety and effectiveness as shown in bench and animal studies.

Table of Substantial Equivalence

Device	Nerve Cuff	Surgisis Nerve Cuff	Cova ORTHO-NERVE
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated	Biom' Up SA
510(k) Number	K132660	K031069	K103081
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.	Indicated for peripheral nerve injuries where there is no gap or where a gap closure is achieved by flexion of the extremity.
Material	Porcine small intestinal	Porcine small intestinal	Porcine collagen

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		submucosa Primarily Types I, III, IV and VI collagen	submucosa Primarily Types I, III, IV and VI collagen	
	Dimensions	1.5 - 10 mm (diameter) x 1-5 cm length (slit tubes) and sheets of sizes 15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm	2, 5, 7 mm (diameter) x 5 cm length (nominal) (tubes)	15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm sheets
	Thickness	100 µm to 1000 µm	100 µm to 1000 µm	NA
	Sterilization	Ethylene oxide	Ethylene Oxide	Gamma irradiation
	Pliable	Yes	Yes	Yes
	Wettable	Yes	Yes	Yes
	Resorbable	Yes	Yes	Yes
	Shelf-life	18 months	18 months	24 months
	Packaging	Tray/Pouch or double pouch	Tray/Double-peel pouch	Double-peel package

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510(k) Summary

December 5, 2013

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

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

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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 and similar to its other predicate, Cova ORTHO-NERVE (K103081) manufactured by Biom' Up S.A (France). 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 predicates Surgisis Nerve Cuff and Cova ORTHO-NERVE, 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

Test	Results	Conclusions
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 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.	Non-irritant at 24 weeks after implantation
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 0.06 EU/ml as required by FDA for devices contacting cerebrospinal tissue.	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 devices in terms of safety and effectiveness as shown in bench and animal studies.

Table of Substantial Equivalence

Device	**Nerve Cuff**	**Surgisis Nerve Cuff**	**Cova ORTHO-NERVE**
Manufacturer	Cook Biotech Incorporated	Cook Biotech Incorporated	Biom' Up SA
510(k) Number	K132660	K031069	K103081
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.	Indicated for peripheral nerve injuries where there is no gap or where a 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	Porcine collagen
Dimensions	1.5 - 10 mm (diameter) x 1-5 cm length (slit tubes) and sheets of sizes 15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm	2, 5, 7 mm (diameter) x 5 cm length (nominal) (tubes)	15 x 25, 20 x 30, 30 x 40 and 40 x 60 mm sheets
Thickness	100 µm to 1000 µm	100 µm to 1000 µm	NA
Sterilization	Ethylene oxide	Ethylene Oxide	Gamma irradiation
Pliable	Yes	Yes	Yes
Wettable	Yes	Yes	Yes
Resorbable	Yes	Yes	Yes
Shelf-life	18 months	18 months	24 months
Packaging	Tray/Pouch or double pouch	Tray/Double-peel pouch	Double-peel package