

APR 03 2014

510(k) SUMMARY

K131541

1. Applicant Information

Applicant Name: Collagen Matrix, Inc.
Address: 15 Thornton Road
Oakland, New Jersey 07436
Telephone: (201) 405-1477
Fax: (201) 405-1355
Contact Person: Peggy Hansen, RAC
VP, Clinical, Regulatory, QA, and Marketing
Date Prepared: March 31, 2014

2. Name of the Device

Device Common Name: Nerve Cuff
Device Trade Name: Flexible Collagen Nerve Cuff
Device Classification Name: Nerve cuff
882.5275
JXI
Class II

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): Collagen Nerve Cuff
K012814

Silastic® Nerve Cuff
Pre-amendment Device

4. Description of the Device

Flexible Collagen Nerve Cuff is a resorbable, flexible type I collagen tubular matrix that provides both an encasement for peripheral nerve injuries as well as protection of the neural environment. Flexible Collagen Nerve Cuff is designed to be an interface between the nerve and the surrounding tissue (e.g., to prevent ingrowth of scar tissue). When placed at the terminal end of a nerve, the Flexible Collagen Nerve Cuff is designed to prevent formation of neuroma. When hydrated, Flexible Collagen Nerve Cuff is a flexible collagen conduit where the crimped walls provide a kink-resistant property to the tube. It is supplied sterile, non-pyrogenic, in various sizes and for single use only.

5. Indications for Use / Intended Use

Flexible Collagen Nerve Cuff is used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve in the foot to reduce the formation of symptomatic or painful neuroma.

6. Summary/Comparison of Technical Characteristics

Flexible Collagen Nerve Cuff is the identical product to the Company's currently marketed Neuroflex™ Collagen Nerve Cuff. The 510(k) premarket notification was submitted for expanded indications.

Parameter	Flexible Collagen Nerve Cuff (This submission)	Collagen Nerve Cuff K012814	Silastic® Nerve Cuff
Indications for Use	Intended for use in the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve in the foot to reduce the formation of symptomatic or painful neuroma.	Intended for use in the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.	Intended to be used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).
Material	Type I collagen	Type I collagen	Silicone
Source	Bovine tendon	Bovine tendon	Synthetic
Form	Tubular matrix	Tubular matrix	Tubular matrix
Color	White to off-white	White to off-white	Opaque
Sizes	2 mm ID x 2.5 cm length 2.5 mm ID x 2.5 cm length 3 mm ID x 2.5 cm length 4 mm ID x 2.5 cm length 5 mm ID x 2.5 cm length 6 mm ID x 2.5 cm length	2 mm ID x 2.5 cm length 2.5 mm ID x 2.5 cm length 3 mm ID x 2.5 cm length 4 mm ID x 2.5 cm length 5 mm ID x 2.5 cm length 6 mm ID x 2.5 cm length	3.3 mm ID x 1.0 cm length 4.1 mm ID x 1.0 cm length 4.8 mm ID x 1.0 cm length 5.3 mm ID x 1.3 cm length 6.1 mm ID x 1.3 cm length 7.1 mm ID x 1.3 cm length 7.9 mm ID x 1.5 cm length 8.6 mm ID x 1.5 cm length 9.9 mm ID x 1.5 cm length 10.7 mm ID x 1.5 cm length 11.7 mm ID x 1.8 cm length 13.7 mm ID x 1.8 cm length
Mechanical Strength	Can be sutured	Can be sutured	Can be sutured
Resorbable	Yes	Yes	No
Crosslinked	Yes	Yes	No
Porosity/ Permeability	Semi-permeable. Permeable to nutrients and macromolecules	Semi-permeable Permeable to nutrients and macromolecules	Non-permeable
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Sterility	Sterile, SAL 10 ⁻⁶ Gamma irradiation	Sterile, SAL 10 ⁻⁶ Gamma irradiation	Sterile
Pyrogenicity	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml	Unknown
Single Use/Reuse	Single use only	Single use only	Single use only

Parameter	Flexible Collagen Nerve Cuff (This submission)	Collagen Nerve Cuff K012814	Silastic® Nerve Cuff
Packaging	Double peel package	Double peel package	Sterile vials of distilled water

Nonclinical Tests Submitted

The substantial equivalence of the Flexible Collagen Nerve Cuff and its predicate device was demonstrated based on an evaluation of the expanded indications.

In vitro characterization studies included evaluation of physical properties such as suture strength, kink resistance, and an evaluation of physicochemical properties such as product permeability and hydrothermal transition temperature. The characterization test results of the subject device were equivalent to those of the predicate device, given that there has been no change to the device itself.

The Flexible Collagen Nerve Cuff material was evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The representative product passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices.

Test	Results	Conclusions
Cytotoxicity - Agarose Overlay	No evidence of causing any cell lysis or toxicity.	Non-cytotoxic
Sensitization - Guinea Pig Maximization	No evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig test.	Non-sensitizer
Intracutaneous Reactivity	Under the conditions of the study, there was no irritation or toxicity from the extract injected intracutaneously into rabbits.	Non-irritant, non-toxic
Acute Systemic Toxicity	No mortality or evidence of systemic toxicity	Non-toxic (acute systemic)
Genotoxicity - Bacterial Reverse Mutation	Non-mutagenic to <i>Salmonella typhimurium</i> and to <i>Escherichia coli</i> strain WP2uvra	Non-mutagenic
Mouse Lymphoma Assay	None of the test article treatments induced substantial increases in the number of revertant colonies.	Non-mutagenic
In Vivo Mouse Micronucleus Assay	None of the mice treated with the test article preparations exhibited overt signs of toxicity either immediately post-treatment or during the induction period. The levels of micronucleated cells were within normal negative ranges.	Non-mutagenic

Test	Results	Conclusions
Pyrogenicity - Rabbit Pyrogen	Non-pyrogenic	Non-pyrogenic
Muscle Implantation	The macroscopic reaction was not significant compared with the USP negative control implant material. Microscopically, the test article was classified as a nonirritant as compared to the USP negative control article.	Non-irritant
Subacute/ Subchronic/ Chronic Toxicity	Minimum tissue reaction up to 24 weeks of implantation and no adverse tissue reaction to the host.	Non toxic (subacute, subchronic, chronic)

Viral inactivation studies were performed to ensure the viral safety of the product.

Clinical Test Submitted

A clinical study was submitted that evaluated the use of the Flexible Collagen Nerve Cuff in the management of painful neuromas of the foot. A total of 50 patients underwent excision of painful single or multiple neuromas with the end of the resected nerve sutured into the Flexible Collagen Nerve Cuff subject device. Each patient preoperatively was asked to describe the amount of pain he or she was experiencing on a scale from 1 to 10, with 10 indicating the most severe pain. In the telephone interview conducted during this study, the same question was asked of each patient following revision. Patient ages ranged from 16 to 77 years, with a mean of 54 years. In all, 30 right and 20 left sides were operated, and 1 patient had bilateral involvement. Mean follow-up was 36 months (6-55 months). There were a total of 60 nerves that underwent conduit procedures in the foot. The results showed a 93% success rate of reducing pain for the treatment of neuroma in the foot.

A clinical literature review and meta-analysis was further conducted to compare the results of the clinical study of the Flexible Collagen Nerve Cuff subject device with published studies of the Silastic Nerve Cuff predicate device and nerve excision alone, specifically for treatment of nerve ends of the foot. The analysis showed that the Flexible Collagen Nerve Cuff performs substantially equivalent to its predicate device (Silastic Nerve Cuff) with respect to reduction of pain post-operatively. In addition, both devices show clinically significant improvement in pain reduction over the excision-only control group.

Conclusions Drawn from Non-clinical and Clinical Studies

The results of the material evaluation, *in vitro* product characterization studies, biocompatibility studies, animal and clinical studies show that the Flexible Collagen Nerve Cuff is safe and substantially equivalent to the predicate device. The expanded indication for use does not affect the safety and performance of the device.



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

April 3, 2014

Collagen Matrix, Inc.
Ms. Peggy Hansen, Vice President
Clinical Regulatory, QA & Marketing
15 Thornton Road
Oakland, NJ 07436

Re: K131541 .

Trade/Device Name: Neuroflex™ Collagen Nerve Cuff
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: March 6, 2014
Received: March 7, 2014

Dear Ms. Hansen:

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

Page 2 – Ms. Peggy Hansen

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, PhD, MS
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)
K131541

Device Name
Flexible Collagen Nerve Cuff

Indications for Use (Describe)
Flexible Collagen Nerve Cuff is used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve in the foot to reduce the formation of symptomatic or painful neuroma.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Joyce M. Whang -S

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

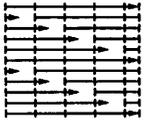
DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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 number."

K131541



Collagen Matrix, Inc.

15 Thornton Road, Oakland, NJ 07436 • Tel: 201-405-1477 • Fax: 201-405-1355

May 24, 2013

FDA CDRH DMC
MAY 29 2013
Received

VIA FEDERAL EXPRESS

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

Re: 510(k) Premarket Notification (Traditional)
Flexible Collagen Nerve Cuff

Dear Sir or Madam:

Pursuant to 21 CFR Part 807, Subpart E, Premarket Notification Procedures, Section 807.81, Collagen Matrix, Inc. is submitting this 510(k) Premarket Notification for its Flexible Collagen Nerve Cuff. Collagen Matrix has determined that Flexible Collagen Nerve Cuff is substantially equivalent to its current legally marketed Collagen Nerve Cuff and intends to manufacture and market the device.

The above-referenced device was originally cleared under 510(k) number K012814. The reason for this submission is to expand the Indications for Use of the device.

This submission includes an electronic copy of the 510(k) as per the FDA's web instructions. The electronic copy is an exact duplicate of the paper copy.

Trade Name or Proprietary Name: Flexible Collagen Nerve Cuff

Common or Usual Name: Nerve Cuff

Device Classification Name: Nerve cuff

Regulation Number: 882.5275

Product Code: JXI

Device Class: Class II

Name and Address of Manufacturer: Collagen Matrix, Inc.
15 Thornton Road
Oakland, New Jersey 07436

Establishment Registration No.: 2249852

S3

**Name, Address, and Telephone
Number of Contact Person:**

Peggy Hansen, RAC
Vice President, Clinical, Regulatory, QA, and
Marketing
Collagen Matrix, Inc.
15 Thornton Road
Oakland, New Jersey 07436
Tel: (201) 405-1477, ext. 304
Fax: (201) 405-1355
E-mail: phansen@collagenmatrix.com

If you have any questions, please do not hesitate to contact me.

Sincerely,



Peggy Hansen, RAC
Vice President, Clinical, Regulatory, Quality Assurance, and Marketing

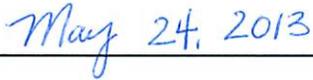
Enclosures (submitted in duplicate – 1 paper copy and 1 electronic copy)

6. TRUTHFUL AND ACCURACY STATEMENT

I certify that, in my capacity as Vice President, Clinical, Regulatory, Quality Assurance, and Marketing and Chief Regulatory Officer of Collagen Matrix, Inc., 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.

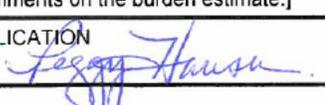


Peggy Hansen, RAC
Vice President, Clinical, Regulatory, Quality Assurance,
and Marketing
Chief Regulatory Officer



Date

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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/cover sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) COLLAGEN MATRIX INC 15 Thornton Road Oakland Bergen NJ 07436 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3886		2. CONTACT NAME Peggy Hansen 2.1 E-MAIL ADDRESS phansen@collagenmatrix.com 2.2 TELEPHONE NUMBER (include Area code) 201-405-1477 304 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 201-405-1355	
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/oc/mdufma) <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice			
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD138256			
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? <input checked="" type="checkbox"/> 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.) <input type="checkbox"/> 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/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> 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)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> 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)  24-May-2013			

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission May 24, 2013	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
------------------------------------	--------------------------------------	---

SECTION A TYPE OF SUBMISSION

<p>PMA</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<p>PMA & HDE Supplement</p> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<p>PDP</p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p>510(k)</p> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<p>Meeting</p> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<p>IDE</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p>Humanitarian Device Exemption (HDE)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p>Class II Exemption Petition</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p>Evaluation of Automatic Class III Designation (De Novo)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p>Other Submission</p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Collagen Matrix, Inc.		Establishment Registration Number (if known) 2249852	
Division Name (if applicable)		Phone Number (including area code) 201-405-1477	
Street Address 15 Thornton Road		FAX Number (including area code) 201-405-1355	
City Oakland	State / Province New Jersey	ZIP/Postal Code 07436	Country USA
Contact Name Peggy Hansen			
Contact Title Vice President, Clinical, Regulatory, QA, and Marketing		Contact E-mail Address phansen@collagenmatrix.com	

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

Company / Institution Name same as above			
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 D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (*specify*):

SECTION D2

REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (*specify*):

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input checked="" type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> 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

- 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	K012814	1	Neuroflex(TM) Collagen Nerve Cuff	1	Collagen Matrix, Inc.
2		2		2	
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

882.5275 Nerve cuff.

Trade or Proprietary or Model Name for This Device		Model Number	
1	Flexible Collagen Nerve Cuff	1	TBD
2		2	
3		3	
4		4	
5		5	

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

1	K012814	2	K060952	3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

- Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code JXI	C.F.R. Section (if applicable) 882.5275	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Neurology		

Indications (from labeling)

Flexible Collagen Nerve Cuff is used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number 2249852	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Collagen Matrix, Inc.		Establishment Registration Number 2249852		
Division Name (if applicable)		Phone Number (including area code) 201-405-1477		
Street Address 15 Thornton Road		FAX Number (including area code) 201-405-1355		
City Oakland		State / Province New Jersey	ZIP Code 07436	Country USA
Contact Name Peggy Hansen		Contact Title Vice President, Clinical, Regulatory, QA, and Marketing		Contact E-mail Address phansen@collagenmatrix.com

(b)(4) Trade Secret Process

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> 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	11137-1	ANSI/AAMI/ISO	Sterilization of health care products - Radiation - requirements for development, validation and routine control of a sterilization process for medical devices	1st edition	04/2006
2	11137-2	ANSI/AAMI/ISO	Sterilization of health care products - Radiation - Establishing the sterilization dose	1st edition	06/2007
3	10993	ISO	Biological evaluation of medical devices	3rd edition	07/2009
4	22442-1, -2, -3	ISO	Animal tissue and their derivatives utilized in the manufacture of medical devices, Parts 1 - 3		12/2007
5	11737-1	ISO	Sterilization of medical devices - microbiological method. Determination of the population of microorganisms on products.		04/2006
6	11607-1	ISO	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems.		04/2006
7					

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

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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 the Chief Information Officer (HFA-710)
 5600 Fishers Lane
 Rockville, Maryland 20857

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.

May 24, 2013

VIA FEDERAL EXPRESS

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

Re: 510(k) Premarket Notification (Traditional)
Flexible Collagen Nerve Cuff

Dear Sir or Madam:

Pursuant to 21 CFR Part 807, Subpart E, Premarket Notification Procedures, Section 807.81, Collagen Matrix, Inc. is submitting this 510(k) Premarket Notification for its Flexible Collagen Nerve Cuff. Collagen Matrix has determined that Flexible Collagen Nerve Cuff is substantially equivalent to its current legally marketed Collagen Nerve Cuff and intends to manufacture and market the device.

The above-referenced device was originally cleared under 510(k) number K012814. The reason for this submission is to expand the Indications for Use of the device.

This submission includes an electronic copy of the 510(k) as per the FDA's web instructions. The electronic copy is an exact duplicate of the paper copy.

Trade Name or Proprietary Name: Flexible Collagen Nerve Cuff

Common or Usual Name: Nerve Cuff

Device Classification Name: Nerve cuff

Regulation Number: 882.5275

Product Code: JXI

Device Class: Class II

Name and Address of Manufacturer: Collagen Matrix, Inc.
15 Thornton Road
Oakland, New Jersey 07436

Establishment Registration No.: 2249852

**Name, Address, and Telephone
Number of Contact Person:**

Peggy Hansen, RAC
Vice President, Clinical, Regulatory, QA, and
Marketing
Collagen Matrix, Inc.
15 Thornton Road
Oakland, New Jersey 07436
Tel: (201) 405-1477, ext. 304
Fax: (201) 405-1355
E-mail: phansen@collagenmatrix.com

If you have any questions, please do not hesitate to contact me.

Sincerely,

Peggy Hansen, RAC
Vice President, Clinical, Regulatory, Quality Assurance, and Marketing

Enclosures (submitted in duplicate – 1 paper copy and 1 electronic copy)

Indications for Use

510(k) Number (if known): _____

Device Name: Flexible Collagen Nerve Cuff

Indications for Use:

Flexible Collagen Nerve Cuff is used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

1. Applicant Information

Applicant Name: Collagen Matrix, Inc.
Address: 15 Thornton Road
Oakland, New Jersey 07436
Telephone: (201) 405-1477
Fax: (201) 405-1355
Contact Person: Peggy Hansen, RAC
VP, Clinical, Regulatory, QA, and Marketing
Date Prepared: May 7, 2013

2. Name of the Device

Device Common Name: Nerve Cuff
Device Trade Name: Flexible Collagen Nerve Cuff
Device Classification Name: Nerve cuff
882.5275
JXI
Class II

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): Collagen Nerve Cuff
K012814

4. Description of the Device

Flexible Collagen Nerve Cuff is a resorbable, flexible type I collagen tubular matrix that provides both an encasement for peripheral nerve injuries as well as protection of the neural environment. Flexible Collagen Nerve Cuff is designed to be an interface between the nerve and the surrounding tissue (e.g., to prevent ingrowth of scar tissue). When placed at the terminal end of a nerve, the Flexible Collagen Nerve Cuff is designed to prevent formation of neuroma. When hydrated, Flexible Collagen Nerve Cuff is a flexible collagen conduit where the crimped walls provide a kink-resistant property to the tube. It is supplied sterile, non-pyrogenic, in various sizes and for single use only.

5. Intended Use

Flexible Collagen Nerve Cuff is used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.

6. Summary/Comparison of Technical Characteristics

Flexible Collagen Nerve Cuff is the identical product to the Company's currently marketed Neuroflex™ Collagen Nerve Cuff. The 510(k) premarket notification was submitted for expanded indications.

Nonclinical Tests Submitted

The substantial equivalence of the Flexible Collagen Nerve Cuff and its predicate device was demonstrated based on an evaluation of the expanded indications.

In vitro characterization studies included evaluation of physical properties such as suture strength, kink resistance, and an evaluation of physicochemical properties such as product permeability and hydrothermal transition temperature. The characterization test results of the subject device were equivalent to those of the predicate device, given that there has been no change to the device itself.

The Flexible Collagen Nerve Cuff material was evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The representative product passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices.

Viral inactivation studies were performed to ensure the viral safety of the product.

Clinical Test Submitted

A clinical study was submitted that evaluated the use of the Flexible Collagen Nerve Cuff in the management of painful neuromas of the foot and ankle.

Conclusions Drawn from Non-clinical and Clinical Studies

The results of the material evaluation, *in vitro* product characterization studies, biocompatibility studies, animal and clinical studies show that the Flexible Collagen Nerve Cuff is safe and substantially equivalent to the predicate device. The expanded indication for use does not affect the safety and performance of the device.

6. TRUTHFUL AND ACCURACY STATEMENT

I certify that, in my capacity as Vice President, Clinical, Regulatory, Quality Assurance, and Marketing and Chief Regulatory Officer of Collagen Matrix, Inc., 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.

Peggy Hansen, RAC
Vice President, Clinical, Regulatory, Quality Assurance,
and Marketing
Chief Regulatory Officer

Date

7. CLASS III SUMMARY AND CERTIFICATION

Class III Summary and Certification is not applicable to this device.

8. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

No financial support was provided by Collagen Matrix, Inc. for the clinical data presented in this submission.

9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

9.1 Sterilization

Sterilization is conducted in accordance with ISO 11137 *Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization*, and ISO 11737 *Sterilization of Medical Devices - Microbiological Method - Determination of the population of microorganisms on products*.

9.2 Biocompatibility

The biocompatibility of the finished product was tested according to ISO 10993 *Biological Evaluation of Medical Devices*.

9.3 Animal Tissue Control

The bovine tendon animal tissue is controlled in accordance with the following ISO standards:

- ISO 22442-1 *Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 1 Analysis and Risk Management*
- ISO 22442-2 *Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 2 Controls on Sourcing, Collection, and Handling*
- ISO 22442-3 *Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents*

9.4 Packaging

Selection, qualification, validation of packaging were conducted in accordance with ISO 11607 *Packaging for Terminally Sterilized Medical Devices - Requirements for Materials, Sterile Barrier Systems, and Packaging Systems*.

Standards Data Reports (Form FDA 3654) for the above-referenced standards are included in Appendix 9-A.

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 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing

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?

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 510(k)?

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
ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Categorization of medical devices	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Medical device categorized as an Implant device with tissue/bone contact and duration of contact being longer than 30 days

DESCRIPTION

The tests appropriate for an implant device contacting tissue/bone for longer than 30 days were identified.

JUSTIFICATION

The categorization was based on the intended use of the device.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Testing	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Testing was performed on the final product and materials processed in the same manner as the final product.

DESCRIPTION

Selected tests were performed per applicable ISO 10993 standards or equivalent methods.

JUSTIFICATION

Choice of test procedures took into account the factors listed in the standard.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Selection of biological evaluation tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Evaluation included both a study of relevant experiences and actual testing.

DESCRIPTION

Selected tests were performed per applicable ISO 10993 standards or equivalent methods.

JUSTIFICATION

Selected tests were adequate to confirm safety of the final product for its intended use.

* 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

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 10993-3 Biological evaluation of medical devices - Part 3: 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)?

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

ISO 10993-3 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Genotoxicity tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Three tests for assessing genotoxicity were selected: bacterial reverse mutation and mouse lymphoma assay

DESCRIPTION

The finished product was tested in two in vitro studies and one in vivo study to evaluate mutagenic potential.

JUSTIFICATION

The main component of concern is the residual glutaraldehyde crosslinking agent. These studies support the safe levels allowed.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Carcinogenicity tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Risks adequately assessed or managed without generating new carcinogenicity test data.

DESCRIPTION

Carcinogenicity tests were not performed.

JUSTIFICATION

Components and degradation products are natural metabolites of the body. No increased risk of carcinogenicity based on risk anal.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Reproductive and developmental toxicity tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Risks adequately assessed or managed without generating new reproductive and developmental test data.

DESCRIPTION

Reproductive and developmental toxicity tests were not performed.

JUSTIFICATION

Risk assessment ruled out the risk of reproductive and developmental toxicity.

* 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

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 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 2-64

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
ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Sample preparation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

Test was performed on the material itself

DESCRIPTION

The test material was cut into 1 cm x 1 cm portions

JUSTIFICATION

The system suitability was confirmed, where the negative control had a grade of 0 and the positive control had a zone of lysis.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Test procedures	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

Test selected was the agar diffusion test (indirect contact).

DESCRIPTION

The test article was placed on the solidified agarose surface in three separate cell culture wells.

JUSTIFICATION

Product does not contain leachables that cannot diffuse through the agar layer or that would react with agar.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.5	Determination of cytotoxicity	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

Cytotoxicity is determined by qualitative means

DESCRIPTION

Qualitative evaluation was performed according to the standard.

JUSTIFICATION

Appropriate method of determination based on test procedure selected.

* 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

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 10993-6 Biological evaluation of medical devices - Part 6: Tests 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.

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
ISO 10993-6 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Test methods, general aspects	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Test model selected was subcutaneous implantation in the rat.

DESCRIPTION
Test article implanted was the finished product.

JUSTIFICATION
To determine the potential for a local irritant or toxic response to material implanted in direct contact with subcutaneous tissue.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

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 10993-10 Biological evaluation of medical devices - Part 10: 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 # 2-87

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 510(k)?

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

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	Irritation tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

In vivo tests were selected and performed with the extracts of the finished product.

DESCRIPTION

A 0.2 ml dose of the test article extract was injected by the intracutaneous route into five separate sites on the back of rabbits.

JUSTIFICATION

The extract was evaluated for intracutaneous reactivity, because it is an implantable device.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed hypersensitivity tests	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Maximization test for delayed hypersensitivity selected in the guinea pig maximization model.

DESCRIPTION

Test article extract intradermally injected and occlusively patched to test guinea pigs. Test and controls receive challenge patch.

JUSTIFICATION

Selected as one of the appropriate test model for delayed hypersensitivity study.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

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 10993-11 Biological evaluation of medical devices - Part 11: 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 510(k)?

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

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Acute systemic toxicity (Study design)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Type of species selected was the mouse.

DESCRIPTION

Test conditions performed were in accordance with the standard. Test article extract and controls were injected into mice.

JUSTIFICATION

To determine if leachables extracted from the material would cause acute systemic toxicity following injection into mice.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Repeated exposure systemic toxicity (subacute, subchronic, chronic)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

This test was not selected.

DESCRIPTION

JUSTIFICATION

Product is intended for single use, therefore testing for repeated exposure is not applicable.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

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 11137-1 Sterilization of health care products - Radiation Part 1: Requirements for development, validation and routine control

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-224

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 510(k)?

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

ISO 11137-1 Sterilization of health care products - Radiation -Part 1: Requirements for development, validation and routine control

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Establishing the sterilization dose	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
A knowledge of the number and/or resistance to radiation of the bioburden is obtained and used to set the sterilization dose.

DESCRIPTION
A microbiological laboratory performed determinations of bioburden or product representative of that to be produced routinely.

JUSTIFICATION
The process controls in place result in well-controlled bioburden levels.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
12	Maintaining process effectiveness	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
An interval of time of three months between sterilization dose audits is selected.

DESCRIPTION
Quarterly dose audits are performed for each product family.

JUSTIFICATION
Historical results support the selected frequency of dose audits.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

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 11137-2 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-225

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

ISO 11137-2 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Methods of dose establishment	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Method of dose establishment is Method 1: dose setting using bioburden information.

DESCRIPTION

The stages of Method 1 are performed as specified in the standard without deviation.

JUSTIFICATION

Method 1 is applicable to the product being sterilized.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Auditing sterilization dose	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

An interval of time of three months between sterilization does audits is selected per ISO 11137-1.

DESCRIPTION

Procedure for auditing sterilization dose established using Method 1 is performed as specified in the standard without deviation.

JUSTIFICATION

The dose auditing procedure is applicable to the product and its manufacturing environment.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

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 11607-1 Packaging for terminally sterilized medical devices - Part1: Requirements for materials, sterile barrier systems....

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-193

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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 11607-1 Packaging for terminally sterilized medical devices - Part1: Requirements for materials, sterile barrier systems....

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Materials and preformed sterile barrier systems	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Assessment of microbial barrier properties, compatibility with sterilization process, labeling system, storage and transport

DESCRIPTION
Assessment of the preformed sterile barrier systems included review of test results obtained by the supplier of the materials.

JUSTIFICATION
Material-specific properties are tested by the manufacturer of the materials.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Design and development of requirements for packaging systems	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Design, packaging-system performance, stability testing performed.

DESCRIPTION
Design of packaging system defined in Design Input, performance tested in packaging validation studies, shelf life testing for stability.

JUSTIFICATION
Product provided to customer is sterile with a shelf life of 3 years.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Information to be provided	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Information in section 7.1 is provided

DESCRIPTION
Where applicable information is provided with the sterile barrier system.

JUSTIFICATION
Documentation for the packaging materials and design is kept on file for reference.

* 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.

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 11737-1 Sterilization of medical devices - Microbiological methods - Part 1: determination of a population of microorganisms...

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#14-227	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: _____		

<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>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</p>	<p>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.</p> <p>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</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>
--	---

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 11737-1 Sterilization of medical devices - Microbiological methods - Part 1: determination of a population of microorganisms..

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Selection of product	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Selection and handling of product ensured that product was representative of routine production, including packaging and process.

DESCRIPTION
Product sampling considered timing of the bioburden testing and rationale for inclusion of products in a group.

JUSTIFICATION
Justification for the products grouped together was provided in the sterilization validation report.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Methods for determination and microbial characterization of bioburden	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Removal of microorganisms was selected as the method for determination of bioburden.

DESCRIPTION
The efficiency of removal was considered and the method was validated by the test laboratory.

JUSTIFICATION
Consideration was given to ability of technique to remove microorganisms, types and location on product, viability of microorganisms.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7,8,9	Validation of Method, Routine Determination of Bioburden, Maintenance	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Method was validated. Routine determination of bioburden is performed. Changes to methods are assessed.

DESCRIPTION
The test lab validated the method. determination of bioburden is performed quarterly. Changes to the product, process, method.

JUSTIFICATION
Qualified test lab. Quarterly dose audits. Maintenance of the method are monitored as part of change control and re-validation.

* 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.

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 11737-2 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, vali...

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #14-287

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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 11737-2 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, vali..

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Selection of product	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
Selection and handling of product ensured that product was representative of routine production, including packaging and process.

DESCRIPTION
Bioburden is tested on the entire product, SIP = 1.

JUSTIFICATION
Justification for the selected SIP is provided in the sterilization validation report.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Methods for performing tests of sterility	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
Direct immersion of product in growth medium followed by incubation was the method selected for sterility test.

DESCRIPTION
Aseptic techniques were applied.

JUSTIFICATION
The efficiency of the method was validated by the test laboratory.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7 and 8	Assessment and maintenance of the method for performing tests of sterility	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
Appropriate of the test method was validated. Changes to methods are assessed.

DESCRIPTION
Changes to the product, process, or test method are assessed to determine their effect on the test method

JUSTIFICATION
Qualified test lab. Maintenance of the method are monitored as part of change control and re-validation.

* 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.

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 22442-1 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of Risk Management

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	#N/A _____	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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 ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard?..... If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Title of guidance: _____	<input type="checkbox"/>	<input type="checkbox"/>

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

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 22442-1 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of Risk Management

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2	Risk analysis	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
Identification of risks, hazards and hazardous situations.

DESCRIPTION
Cross-functional project team assembled to perform risk analysis using a questionnaire based on questions identified in the standard.

JUSTIFICATION
All risk areas identified per standard

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.3	Risk evaluation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
All identified risks are evaluated.

DESCRIPTION
Identified risks are evaluated by the Failure Modes and Effects Analysis (FMEA) technique.

JUSTIFICATION
FMEA is a well-accepted method of evaluating risk and determining acceptability.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4	Risk control	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
Separately address the risks related to different categories of viruses and TSE agents.

DESCRIPTION
Risk control are addressed by ISO 22442-2 and ISO 22442-3

JUSTIFICATION
An acceptable level of risk was achieved.

* 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.

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 22442-2 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling.

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ #N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
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? Yes No

Does this standard include acceptance criteria? Yes No
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?..... Yes No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS?..... Yes No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?..... Yes No
If yes, was the guidance document followed in preparation of this 510k? Yes No

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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 22442-2 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Sourcing	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]
Control of species, geography, inspection, certification and traceability

DESCRIPTION
The tissue sourcing is determined and controlled according to the standard

JUSTIFICATION
Sourcing meets current standard for use of animal tissue derivatives in medical devices.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Collection	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]
Technical agreement between manufacturer and supplier

DESCRIPTION
Technical agreement specified responsibilities, specifications, documentation, inspection criteria, SOPs, audits, and traceability.

JUSTIFICATION
To clearly identify the roles, responsibilities and authorities between the manufacturer and supplier.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7 and 8	Handling, storage, and transport	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]
Tissue is handled, stored and transported in accordance with established procedures

DESCRIPTION
Tissue is removed to a separate room for cleaning using dedicated apparatus. The tissue is stored and transported frozen in closed containers.

JUSTIFICATION
Certificates of conformance are provided by the supplier and supplier audits are conducted to ensure appropriate procedures are adhered to.

* 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.

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 22442-3 Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	#N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 22442-3 Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Literature review	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]
A literature review of viral and TSE inactivation was performed.

DESCRIPTION
Evaluation of technical information found in literature was evaluated and determined applicable to current manufacturing process.

JUSTIFICATION
Literature provides scientific evidence of sufficient viral and TSE inactivation/elimination with the use of Sodium Hydroxide Treatment.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Elimination and/or inactivation study of Viruses and TSE agents	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]
Viral inactivation study using select model viruses and similar treatment process

DESCRIPTION
Viral inactivation study was conducted by independent test lab in accordance with approved protocol in a scaled-down process.

JUSTIFICATION
Viral and process steps evaluated were relevant to the animal species and the manufacturing process.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Final Report	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]
Final report was written to summarize data collected.

DESCRIPTION
Final report of the viral inactivation study and literature review was written and filed in the Design History Files and a summary was provided in the 510(k).

JUSTIFICATION
The combined results of the viral inactivation study and literature review provides adequate evidence of sufficient viral and TSE inactivation.

* 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.

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

USP <151> Pyrogen Test

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#14-318	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
USP <151> Pyrogen Test

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Apparatus and Diluents, Temperature Recording, Test Animals	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
Render the apparatus free from pyrogens. use accurate temperature-sensing device. Use healthy, mature rabbits.

DESCRIPTION
House the rabbits in an area of uniform temperature, condition for not more than 7 days.

JUSTIFICATION
Standardization of method.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Procedure	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
Perform test in accordance with procedure

DESCRIPTION
Determine the control temperature of each rabbit. Inject the test solution. Record the temperature at 30-min. intervals 1-3 hours.

JUSTIFICATION
Standardization of method.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Test Interpretation and Continuation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦
Use acceptance criteria provided by the USP procedure

DESCRIPTION
Consider any temperature decreases as zero rise. If no rabbit shows a rise in temperature of 0.5 degrees or more, the product is pyrogen-free.

JUSTIFICATION
Acceptance criteria established in the USP method.

* 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.

10. EXECUTIVE SUMMARY

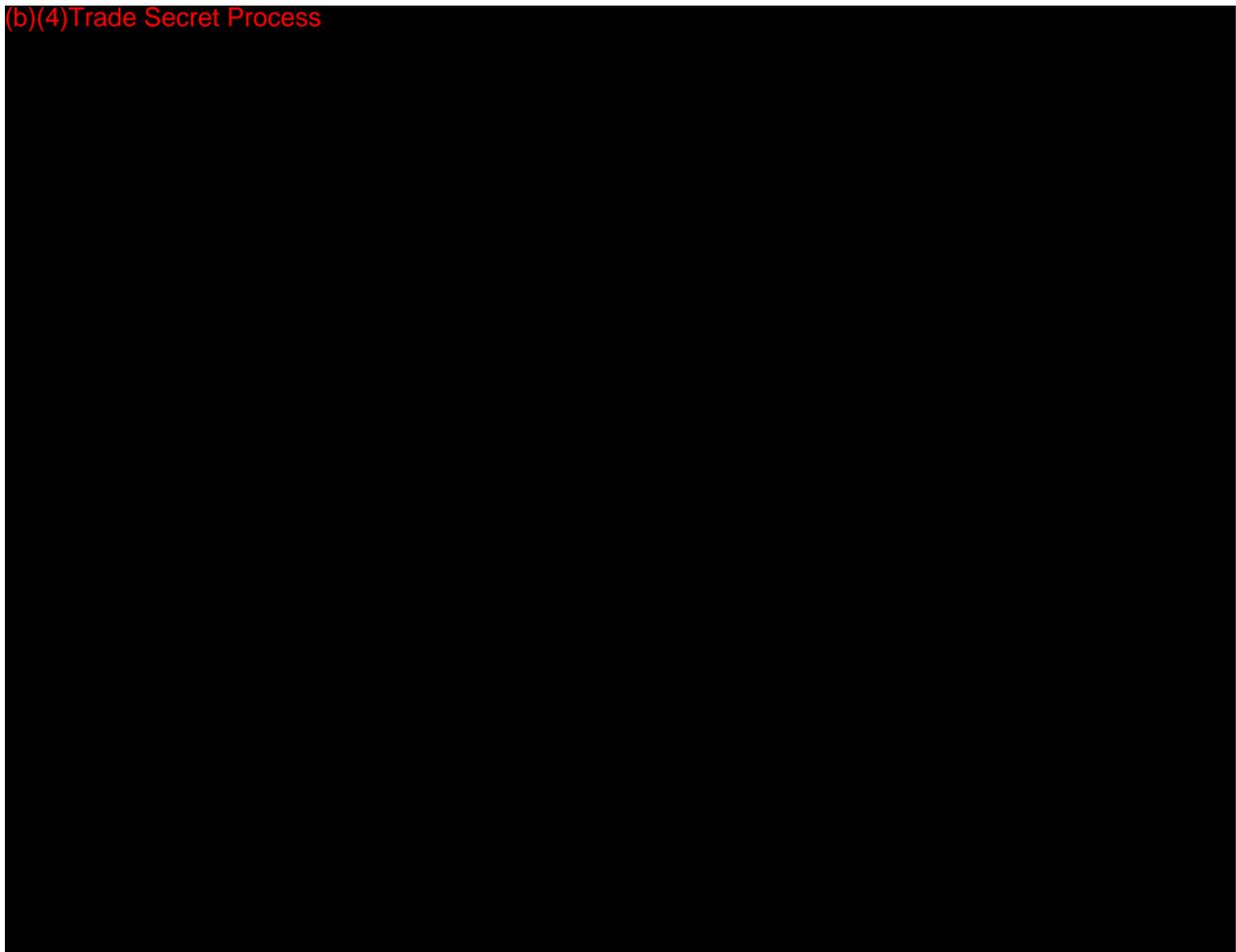
10.1 Brief Description of Device

Flexible Collagen Nerve Cuff is a resorbable, flexible type I collagen tubular matrix that provides both an encasement for peripheral nerve injuries as well as protection of the neural environment. Flexible Collagen Nerve Cuff is designed to be an interface between the nerve and the surrounding tissue (e.g., to prevent ingrowth of scar tissue). When placed at the terminal end of a nerve, the Flexible Collagen Nerve Cuff is designed to prevent formation of neuromas. When hydrated, Flexible Collagen Nerve Cuff is a flexible collagen conduit where the crimped walls provide a kink-resistant property to the tube. It is supplied sterile, non-pyrogenic, in various sizes and for single use only.

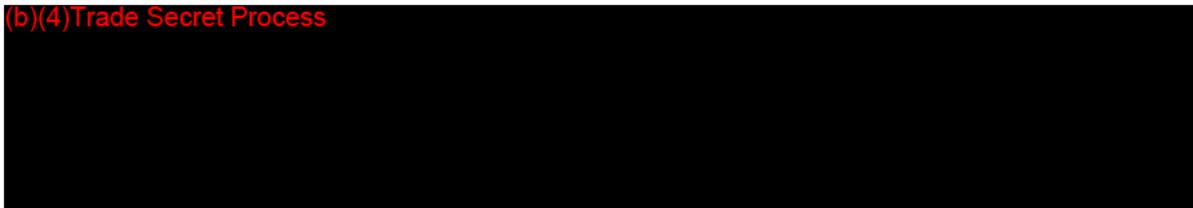
10.2 Design Philosophy

The Flexible Collagen Nerve Cuff (b) device manufactured by Collagen Matrix was originally cleared under 510(k) number K012814. Since the product's launch in 2004, (b)(4)Trade Secret have been sold for use in peripheral nerve repair. Stryker Orthopaedics (Mahwah, NJ) is the current distributor of the product worldwide.

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



10.3 Device Comparison

(b)(4)Trade Secret Process



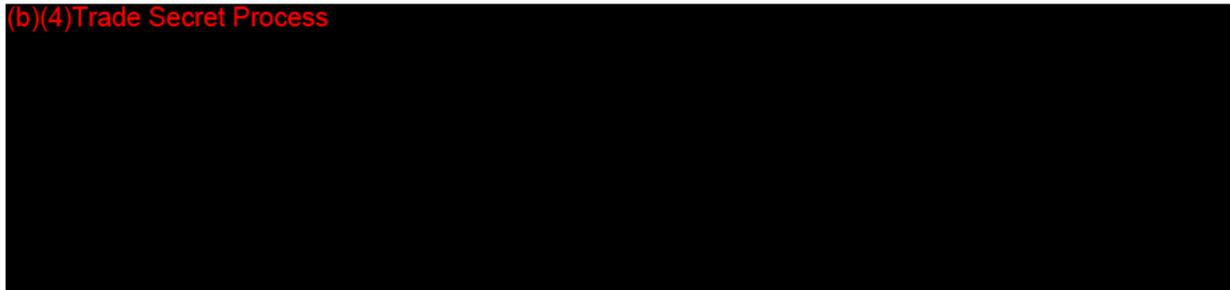
Our claim that the candidate product is substantial equivalent to the predicate devices is based on a comparison of intended use, product design, material characteristics, chemical composition, manufacturing process, and handling properties. (b)(4)Trade Secret Process



The data to support substantial equivalence are provided in this submission.

10.4 Summary of Safety and Performance Testing

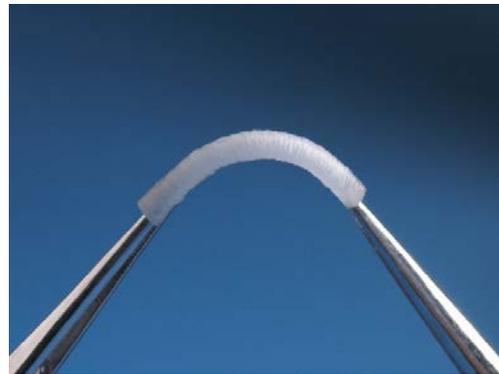
(b)(4)Trade Secret Process



11. DEVICE DESCRIPTION

11.1 Description

Flexible Collagen Nerve Cuff is a resorbable, flexible type I collagen tubular matrix that provides both an encasement for peripheral nerve injuries as well as protection of the neural environment. Flexible Collagen Nerve Cuff is designed to be an interface between the nerve and the surrounding tissue (e.g., to prevent ingrowth of scar tissue). When placed at the terminal end of a nerve, the Flexible Collagen Nerve Cuff is designed to prevent formation of neuromas. When hydrated, Flexible Collagen Nerve Cuff is a flexible collagen conduit where the crimped walls provide a kink-resistant property to the tube. It is supplied sterile, non-pyrogenic, in various sizes and for single use only.



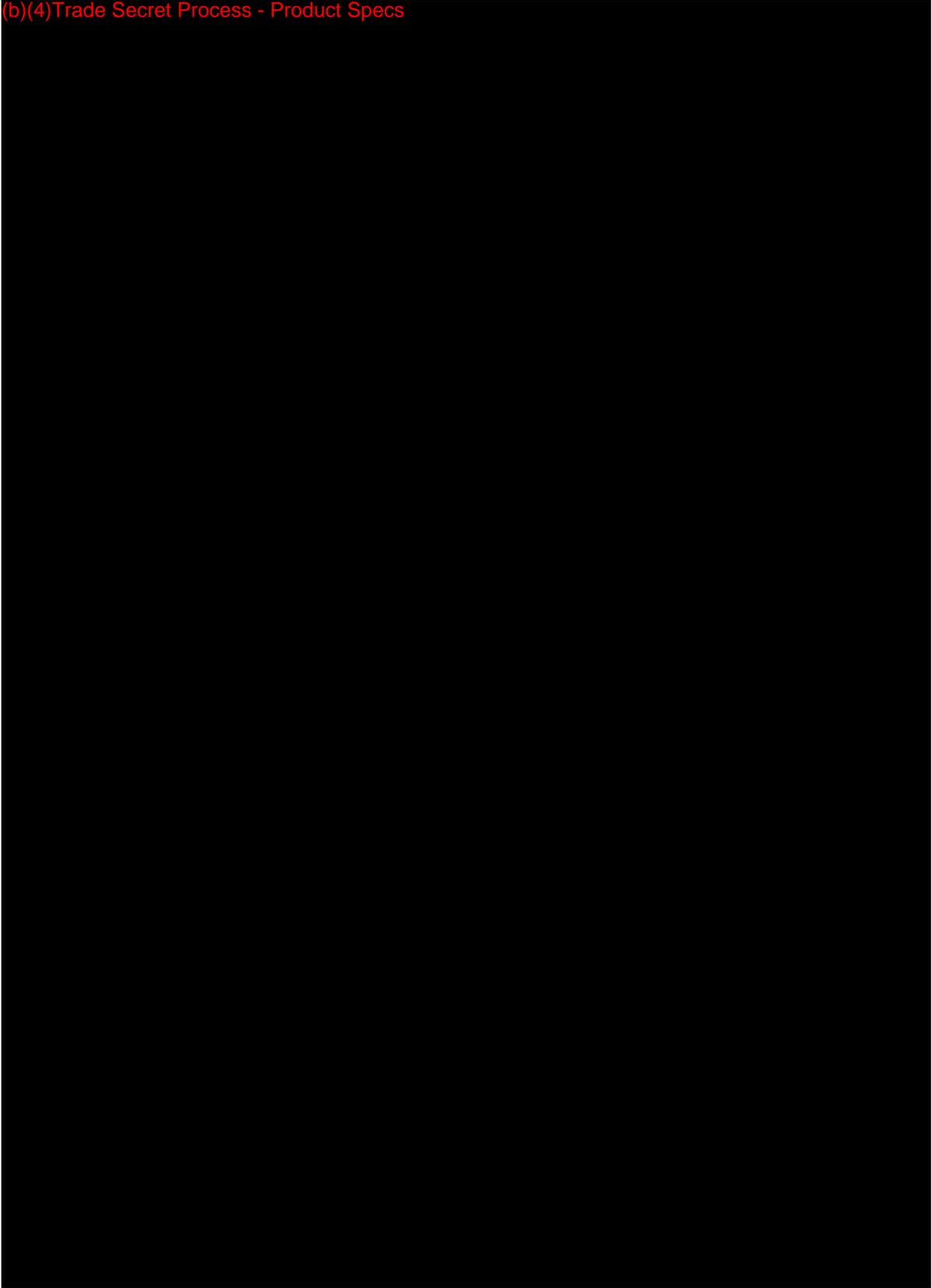
11.2 Intended Use

Flexible Collagen Nerve Cuff is used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.

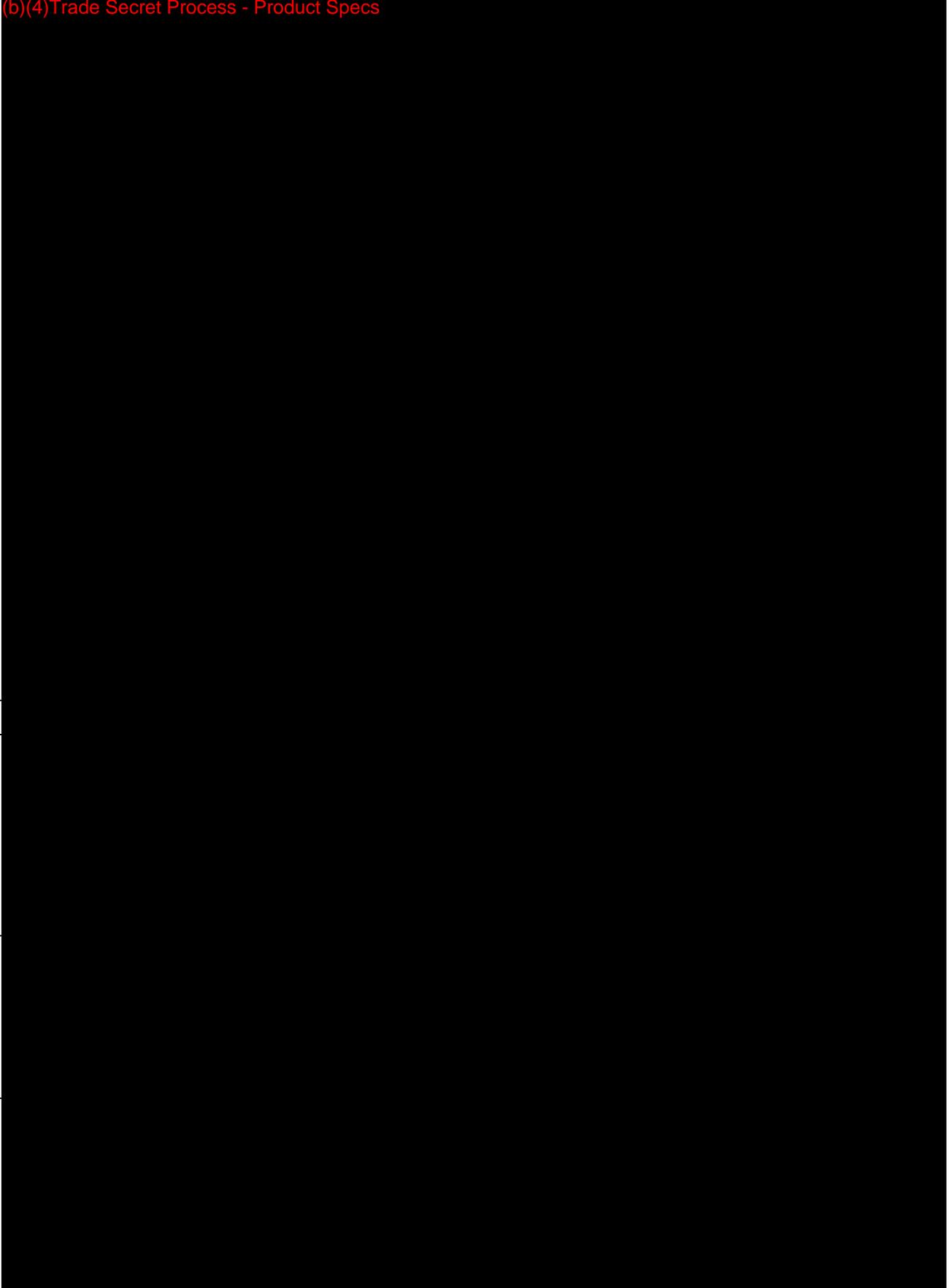
11.3 Materials

(b)(4)Trade Secret Process

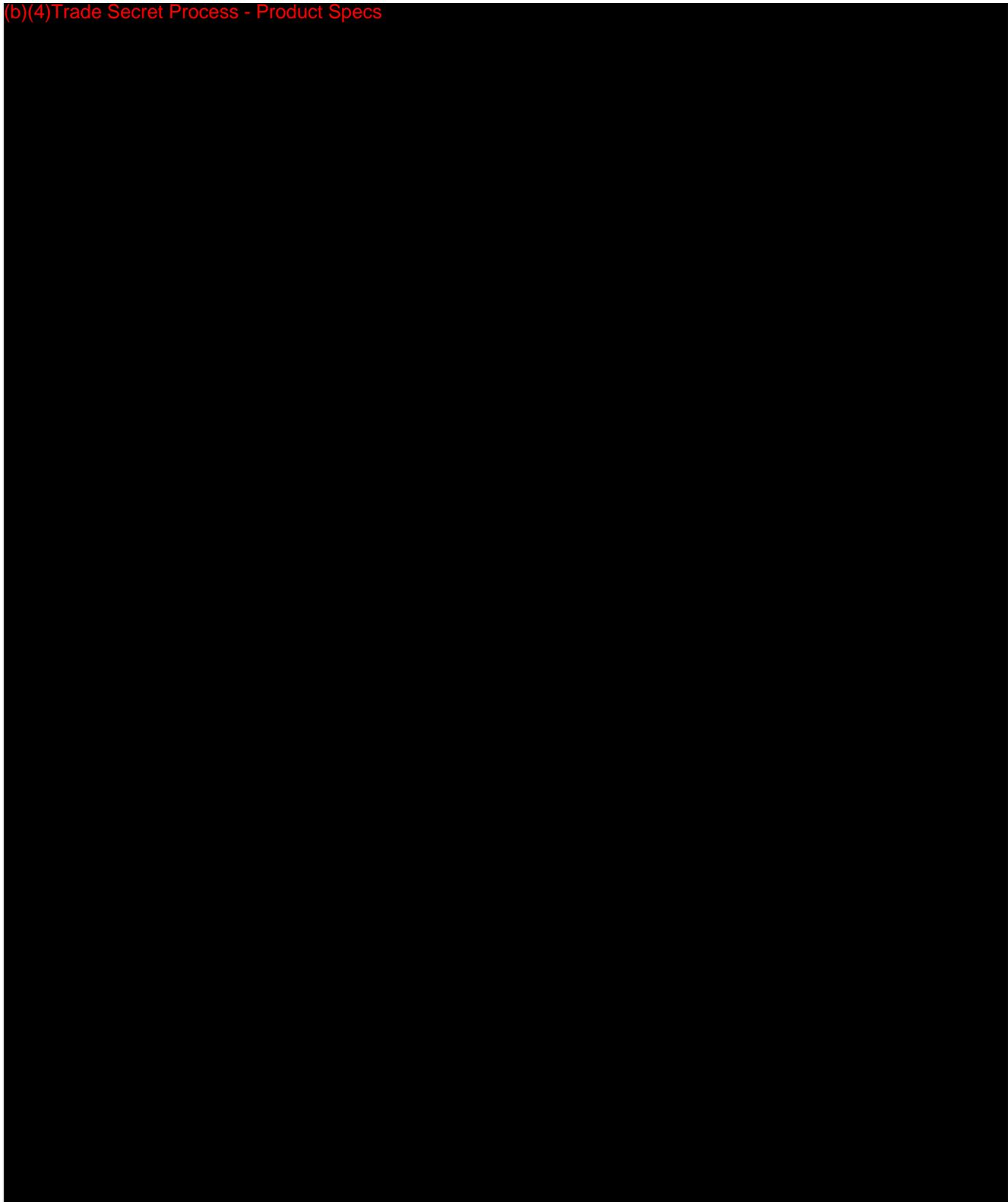
(b)(4)Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs

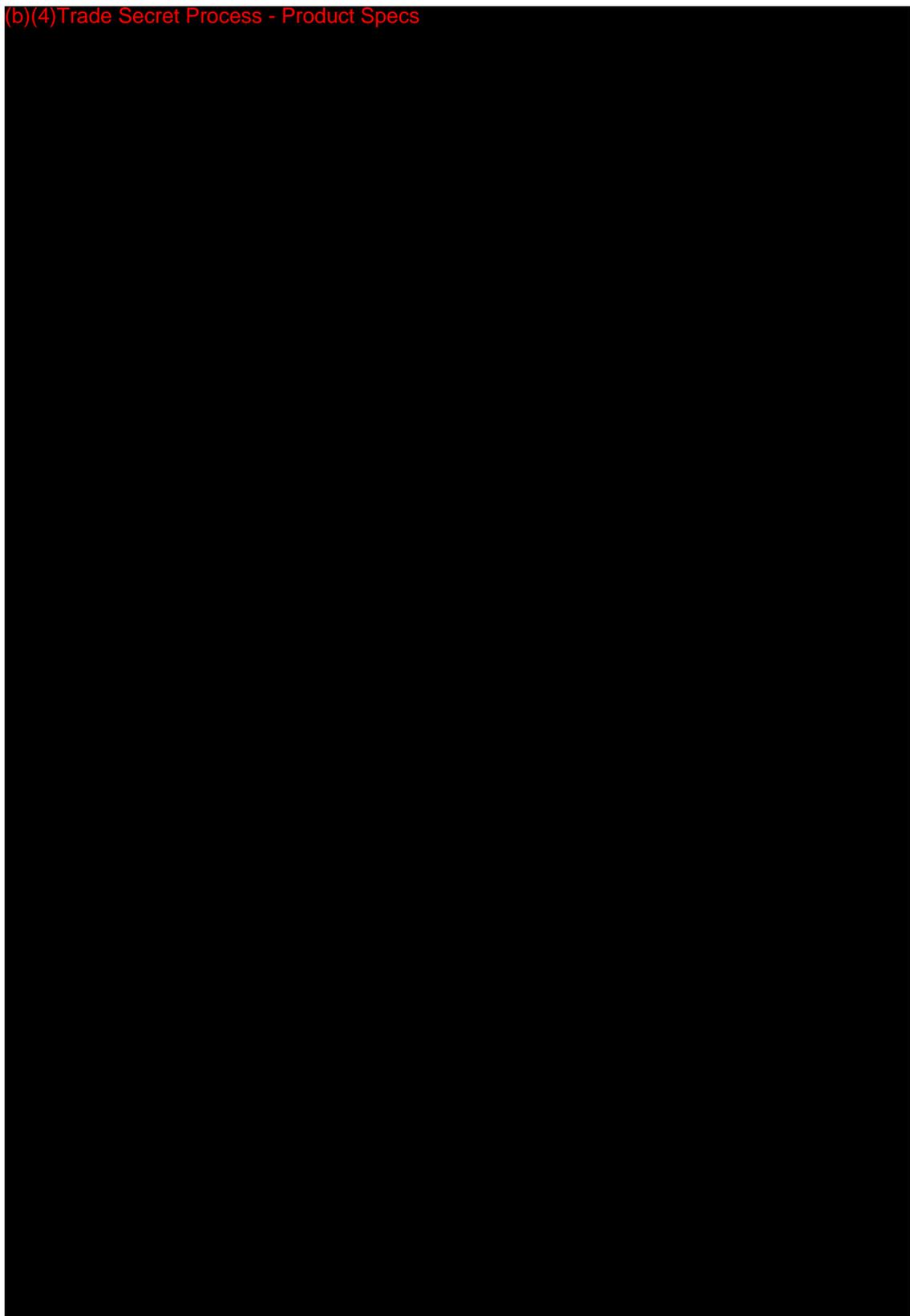


(b)(4) Trade Secret Process - Product Specs



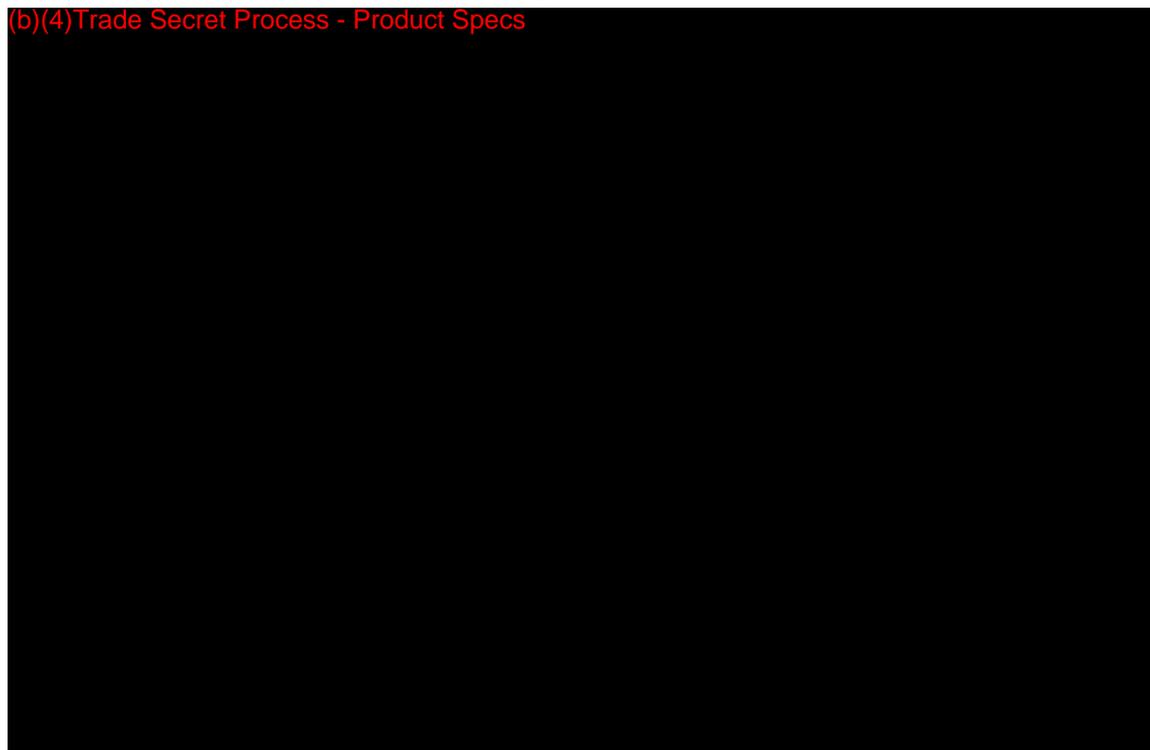
11.5.1 Process Flowchart

(b)(4) Trade Secret Process - Product Specs



11.5.2 Description of Manufacturing Process

(b)(4) Trade Secret Process - Product Specs



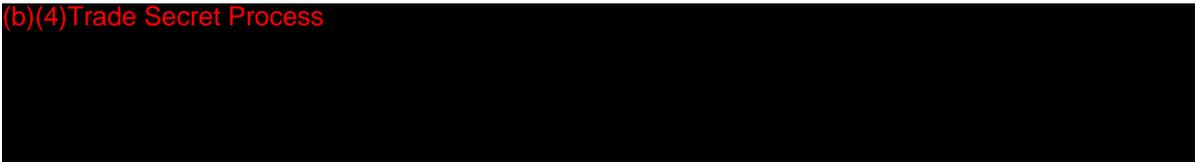
12. SUBSTANTIAL EQUIVALENCE DISCUSSION

12.1 Predicate Device

Based on extensive material characterization testing, Collagen Matrix has demonstrated that its Flexible Collagen Nerve Cuff is substantially equivalent to the following predicate devices:

Collagen Nerve Cuff (Neuroflex™), K012814
Collagen Matrix, Inc., Oakland, NJ

(b)(4)Trade Secret Process

A large black rectangular redaction box covers the content of this section.

12.2 Substantial Equivalence Comparison Table

The Substantial Equivalence Comparison Table is presented on the following page (Table 12-1). As the table shows, the technological characteristics of the Flexible Collagen Nerve Cuff of this submission are substantially equivalent to the predicate device referenced above.

(b)(4)Trade Secret Process

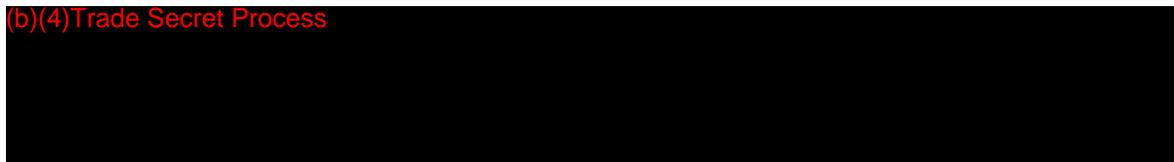
A large black rectangular redaction box covers the content of this section.

Table 12-1. Substantial Equivalence Comparison Chart with Comparative Data*

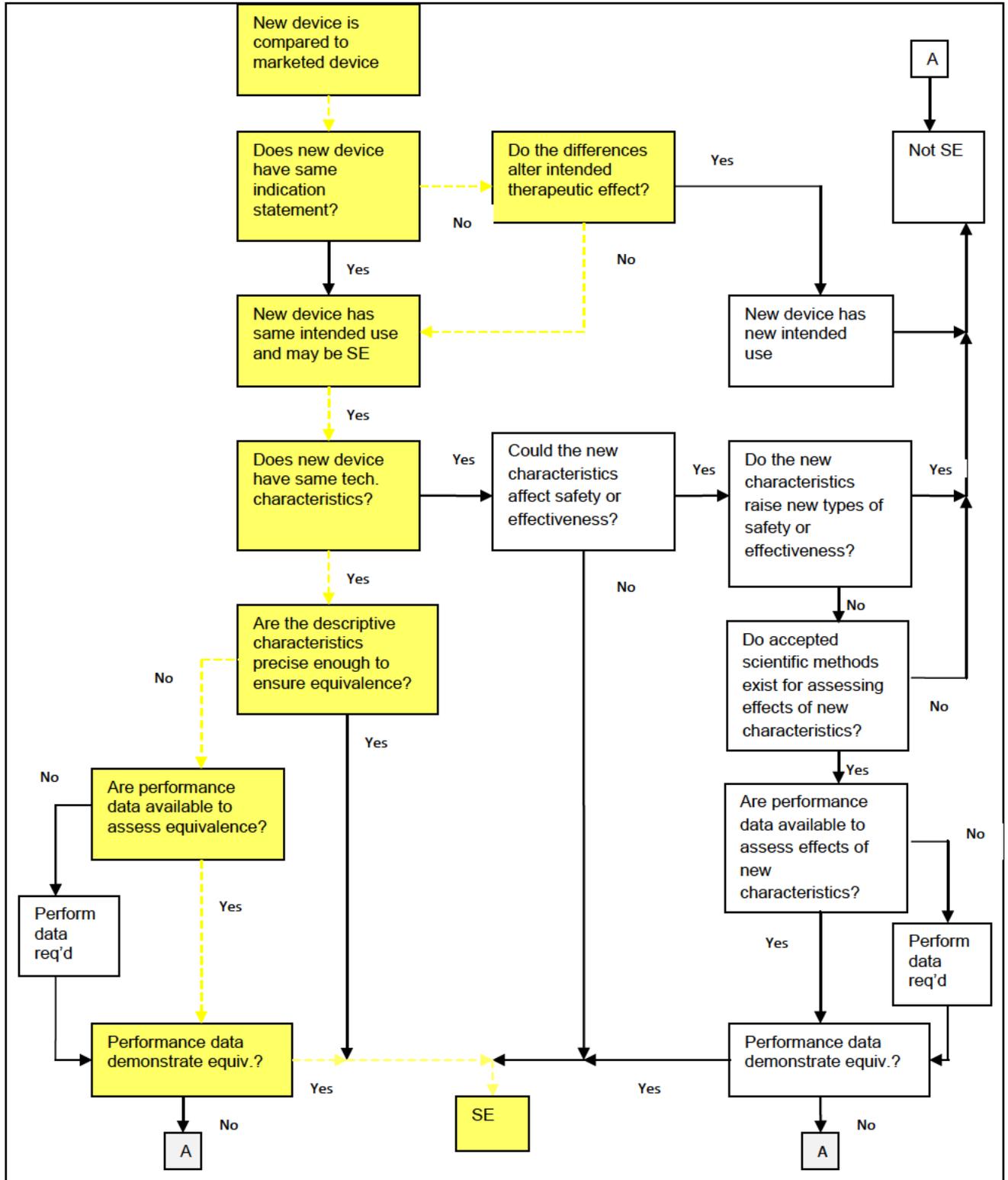
Parameter	Flexible Collagen Nerve Cuff (This submission)	Collagen Nerve Cuff K012814
Indications for Use	Intended for use in the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.	Intended for use in the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.
Material	Type I collagen	Type I collagen
Source	Bovine tendon	Bovine tendon
Form	Tubular matrix	Tubular matrix
Color	White to off-white	White to off-white
Sizes	2 mm ID x 2.5 cm length 2.5 mm ID x 2.5 cm length 3 mm ID x 2.5 cm length 4 mm ID x 2.5 cm length 5 mm ID x 2.5 cm length 6 mm ID x 2.5 cm length	2 mm ID x 2.5 cm length 2.5 mm ID x 2.5 cm length 3 mm ID x 2.5 cm length 4 mm ID x 2.5 cm length 5 mm ID x 2.5 cm length 6 mm ID x 2.5 cm length
(b)(4)Trade Secret Process		
Resorbable	Yes	Yes
(b)(4)Trade Secret Process		
Crosslinked	Yes	Yes
(b)(4)Trade Secret Process		
Biocompatibility	Biocompatible	Biocompatible
Sterility	Sterile, SAL 10 ⁻⁶ Gamma irradiation	Sterile, SAL 10 ⁻⁶ Gamma irradiation

Parameter	Flexible Collagen Nerve Cuff (This submission)	Collagen Nerve Cuff K012814
Pyrogenicity	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml
Single Use/Reuse	Single use only	Single use only
Packaging	Double peel package	Double peel package
Shelf Life	(b)(4)Trade Secret Process	

*Based on information from Company brochures, 510(k) Summaries of Safety and Effectiveness, literature, and in-house testing.

12.3 Substantial Equivalence Decision Flowchart

The following Substantial Equivalence Decision-making Flowchart was used to assess Flexible Collagen Nerve Cuff against the predicate devices.



12.3.1 Description of Substantial Equivalence Flowchart Decisions

Does the new device have same indication statement?

No. The indications for use statement for the Flexible Collagen Nerve Cuff subject device includes an additional indication for minimizing neuroma formation (see Table 12-1).

New device has same intended use and may be substantially equivalent.

Yes. The overall intended use of the subject device and its predicates are the same, which is to provide a protective environment for the healing and repair of injured peripheral nerves.

Does the new device have same technological characteristics, e.g., design, materials, etc.?

Yes. The Flexible Collagen Nerve Cuff subject device is identical to the Collagen Nerve Cuff predicate device.

Are the descriptive characteristics precise enough to show equivalence?

No. While the Flexible Collagen Nerve Cuff subject device is identical to the Collagen Nerve Cuff predicate device, the extension in the indications for use statement to prevent neuromas should be demonstrated with performance data.

Are performance data available to assess equivalence?

Yes. The primary performance data presented are the retrospective clinical study of 50 patients treated with the Flexible Collagen Nerve Cuff for prevention of neuroma formation at nerve ends. This data was also compared with other treatment techniques published in literature; nerve resection only and nerve resection and transposition.

Performance data demonstrate equivalence?

Yes. The results of the comparative testing and performance testing demonstrate that the Flexible Collagen Nerve Cuff is substantially equivalent to its predicate device and that the extension of indications for use does not impact safety or performance of the device.

12.4 Detailed Comparison of Products

The overall product comparisons were presented in the table above. In this section, a detailed comparison of the key difference between the candidate product and the predicate products will be discussed:

- Flexible Collagen Nerve Cuff - SUBJECT DEVICE

(b)(4)Trade Secret Process

In this section, we will review the addition of the indication for use and its impact on the devices substantial equivalence to its predicate.

Parameter	Flexible Collagen Nerve Cuff (This submission)	Collagen Nerve Cuff K012814
Indications for Use	Intended for used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.	Intended for use in the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

(b)(4)Trade Secret Process

The objective of the substantial equivalence comparison is to provide evidence that the difference in the subject device and predicate device does not adversely impact the safety and performance of the subject device, thereby demonstrating “substantial equivalence.”

A review of the verification activities associated with the risk analysis was performed.

Table 12-2. Verification Activities Associated with the Risk Analysis

Device Modification in Indications for Use	Risk	Verification Activity	Acceptance Criteria	Results of Verification
--	------	-----------------------	---------------------	-------------------------

(b)(4)Trade Secret Process

Device Modification in Indications for Use	Risk	Verification Activity	Acceptance Criteria	Results of Verification
(b)(4) Trade Secret Process				

12.5 Conclusions of Comparative Analysis

The only difference in the subject device and the predicate device is the extension of the indications for use to include placement of the Flexible Collagen Nerve Cuff at the end of the injured nerve, in addition to the existing indication for use in bridging a nerve gap. A risk analysis was performed verifying that the extension of the indications for use does not add additional clinical risk nor change the risk to benefit ratio of the subject device.

13. PROPOSED LABELING

The proposed product label and instructions for use of Flexible Collagen Nerve Cuff are provided in this section. The subject device is currently on the market and distributed worldwide by Stryker, Mahwah, NJ with the original indications for use. The new Instructions for Use are included in Appendix 13-A.

13.1 Product Unit Label

The image displays three proposed labeling components for the Neuroflex Flexible Collagen Nerve Cuff, arranged vertically and grouped by brackets on the right side.

Outer box label: This label includes two barcode areas. The top barcode is associated with the reference number **REF CNCF2025** and the size **Size: 2 mm (inner diam) x 2.5 cm (length)**. The bottom barcode is associated with the quantity **QTY 1**. Below the barcodes are two lot numbers: ***+M440CNCF20250D*** and ***+\$\$31404301104231032DZ***. The label also features the **stryker** logo, the distributor information **Mahwah, NJ 07430 USA**, and the manufacturer information **Collagen Matrix, Inc. 15 Thornton Rd Oakland, NJ 07436 USA**. It includes a **LOT** box with **1104231032**, an expiration date of **2014-04**, a **STERILE R** box, a **R_x ONLY** warning, and CE marking **0086**. A temperature range of **15°C/59°F** to **30°C/86°F** is indicated. The **European Authorized Rep:** is **MDSS Schiffgraben 41 D-30175 Hannover Germany**. The label number **NF2025LS Rev 1** is at the bottom right.

Product unit label: This label features the **Neuroflex™ Flexible Collagen Nerve Cuff** title in a box. It includes a **LOT** box with **1104231032**, a **REF** box with **CNCF2025**, and the size **Size: 2 mm ID x 2.5 cm length**. It also shows an expiration date of **2014-04**, a **STERILE R** box, a **R_x ONLY** warning, and CE marking **0086**. The distributor and manufacturer information are repeated: **stryker Mahwah, NJ 07430 USA** and **Collagen Matrix, Inc. 15 Thornton Rd Oakland, NJ 07436 USA**.

Outer box end tab label: This label features the **Neuroflex™** logo, the reference number **REF CNCF2025**, the size **Size: 2 mm ID x 2.5 cm length**, a **LOT** box with **1104231032**, and an expiration date of **2014-04**. A small graphic of the nerve cuff is shown to the right of the text.

INSTRUCTIONS FOR USE

Neuroflex™ Flexible Collagen Nerve Cuff

Intended Use

Neuroflex Flexible Collagen Nerve Cuff is used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.

Description

Neuroflex Flexible Collagen Nerve Cuff is a resorbable, flexible type I collagen tubular matrix that provides both an encasement for peripheral nerve injuries as well as protection of the neural environment. Neuroflex Flexible Collagen Nerve Cuff is designed to be an interface between the nerve and the surrounding tissue (e.g., to prevent ingrowth of scar tissue). When placed at the terminal end of a nerve, the Neuroflex Flexible Collagen Nerve Cuff is designed to prevent formation of neuromas. When hydrated, Neuroflex Flexible Collagen Nerve Cuff is a flexible collagen conduit where the crimped walls provide a kink-resistant property to the tube. It is supplied sterile, non-pyrogenic, in various sizes and for single use only.

Contraindications

Neuroflex Flexible Collagen Nerve Cuff is contraindicated in patients who have acute infections or have a contaminated wound in the immediate area surrounding the peripheral nerve discontinuity and in patients with a known history of allergic reactions to collagen and/or bovine derived products.

Warning

Clinicians should use extra care in screening their patients for any known allergies to collagen or bovine-derived products. Hypersensitivity reactions have been noted with the use of other products containing bovine collagen; therefore, the possibility exists of developing a local sensitivity response to the products.

Precautions

- Avoid tension of the peripheral nerve to be repaired during the entire procedure.
- Closure of the surgical field by layers is recommended to minimize movement and possible dislodging of the entubulated nerve. Excessive and uncontrolled movement of the extremity where nerve repair was performed must be avoided to prevent possible migration of the device and failure of the repair.
- *Neuroflex Flexible Collagen Nerve Cuff* products cannot be re-sterilized or re-used. Open, unused portions of *Neuroflex Flexible Collagen Nerve Cuff* must be discarded. In vivo stability may be adversely affected if re-sterilized. Cross-contamination and infection may occur if re-used.
- Do not use if the product package is damaged or opened.

Directions for Use

1. The injured nerve is surgically exposed at the appropriate incision site according to standard procedures.
2. The proximal and distal segments of the injured nerves are resected to a minimal point where there is no residual intrafascicular scarring.
3. The diameter of the nerve is measured and an appropriate size *Neuroflex Flexible Collagen Nerve Cuff* is selected. The internal diameter of the chosen nerve implant should be slightly larger than the nerve diameter.
4. The nerve implant is hydrated in sterile physiological saline solution for about 5 minutes. Upon hydration, the nerve implant will expand approximately 20-30% of its dry length.

For Gap Closure Applications

5. After hydration the nerve implant is trimmed accordingly to at least a minimum length of 5 mm longer than the measured nerve gap, so that both the proximal and distal nerve stumps can be inserted adequately into each end of the nerve implant.
6. Using atraumatic sutures, pass the suture through the wall of the nerve implant from the outside to inside, at least 1 mm from the end of the tube. Pass the suture transversely through the epineurium of one nerve stump, then back through the inside of the nerve implant to the outside. Gently draw the nerve stump into the nerve implant by pulling the suture such that the nerve stump is drawn into the nerve implant. The final length of insertion of the nerve stump into the nerve implant should be greater than or equal to the nerve diameter. A tensionless secure knot is tied in the suture.

7. Using a syringe gently flush the lumen of the nerve implant with sterile saline or Lactated Ringer's solution USP. Repeat the suturing procedure for the other nerve stump. Repeat the flushing procedure and fill the interior of the nerve implant with saline or Lactated Ringer's solution USP.

For Neuroma Applications

Neuroflex Flexible Collagen Nerve Cuff can be used to minimize neuroma formation in nerve injuries where bridging is not possible or desirable.

5. Using atraumatic sutures, pass the suture through the wall of the nerve implant from the outside to inside, at least 1 mm from the end of the tube. Pass the suture transversely through the epineurium of proximal nerve stump, then back through the inside of the nerve implant to the outside. Gently draw the nerve stump into the nerve implant by pulling the suture such that the nerve stump is drawn into the nerve implant. The final length of insertion of the nerve stump into the nerve implant should be greater than or equal to the nerve diameter. A tensionless secure knot is tied in the suture.

6. Using a syringe gently flush the lumen of the nerve implant with sterile saline or Lactated Ringer's solution USP. The opposing end of the *Neuroflex Flexible Collagen Nerve Cuff* is left open.

Adverse Reactions

Possible complications that can occur with any peripheral nerve surgery may include pain, infection, decrease or increase in nerve sensitivity, and complications associated with use of anesthesia. Minor discomfort in the surgical site may occur for a few days.

Storage

The product should be stored at room temperature. Avoid excessive heat and humidity.

How Supplied

Neuroflex Flexible Collagen Nerve Cuff is available in various diameters.

Safety

The product is manufactured from bovine Achilles tendon, which is classified as tissues with no detected infectivity for Bovine Spongiform Encephalopathy, BSE (World Health Organization Guidelines). The bovine tendon is known to be one of the richest sources of type I collagen that is commercially available.

The manufacturing process for the product meets European and International Standards for animal tissue sourcing, handling and inactivation of Spongiform Encephalopathy (SE) pathogens. This process involves a treatment with sodium hydroxide that is a recognized method of inactivation of SE pathogens.

A viral inactivation study for the product's manufacturing process was conducted by an independent laboratory. In this study key manufacturing steps were evaluated for their ability to inactivate the following viral strains: Bovine Viral Diarrhea (enveloped virus) and Porcine Parvoviridae (non-enveloped virus). The study results showed that each of the manufacturing steps evaluated, including the sodium hydroxide treatment, is effective in inactivating these viruses.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufacturer: Collagen Matrix, Inc.
15 Thornton Road, Oakland, NJ 07436 USA

14. STERILIZATION AND SHELF LIFE

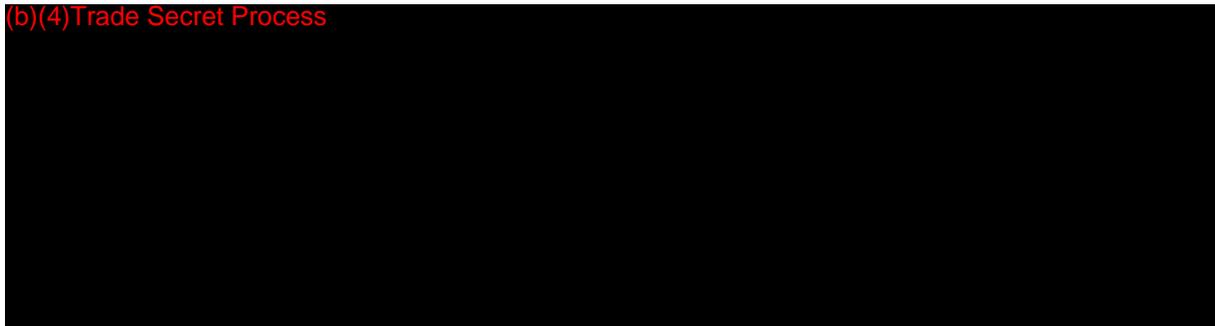
14.1 Sterilization

The method of sterilization is gamma irradiation. The sterilization method has been validated in accordance with ANSI/AAMI/ISO 11137 Sterilization of health care products – Requirements for validation and routine control – Radiation Sterilization. (b)(4)Trade Secret Process The sterility assurance level of the device is 10^{-6} . The validated gamma irradiation dose range is (b)(4)Trade Secret Process. The sterilization validation report is included in Appendix 14-A of this section.

14.2 Shelf Life

A combination of real time product stability testing and package integrity data of the Flexible Collagen Nerve Cuff finished device supports a (b) shelf life for the product. The shelf life study report is provided in Appendix 14-B of this section.

(b)(4)Trade Secret Process



15. BIOCOMPATIBILITY

15.1 Biocompatibility - Clinical Use

The (b) device Neuroflex™ Flexible Collagen Nerve Cuff was cleared under 510(k) number K012814. Since the product's launch in 2004, (b)(4)Trade Secret have been sold for use in peripheral nerve repair worldwide. (b)(4)Trade Secret Process

15.2 Selection of Biocompatibility Studies

The original biocompatibility testing for the product was performed according to the guideline specified in the FDA Blue Book Memorandum G95-1 and ISO 10993-1 under the category of Implant device, tissue/bone contact, permanent duration (>30 days).

Table 15-1. Test Selection for Biocompatibility Studies

Body Contact		Contact Duration C Permanent (>30 days)	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Systemic Toxicity (Acute)	Subchronic Toxicity	Genotoxicity	Implantation	Haemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental
Implant	Tissue	C	X	X	X	X	X	X	X	-	X	X	-

(b)(4)Trade Secret Process

15.3 Biocompatibility Test Results

(b)(4)Trade Secret Process

All test results showed that the Flexible Collagen Nerve Cuff material is biocompatible and safe for human implantation.

All biocompatibility tests were performed at (b)(4)Trade Secret Process

The following tables summarize the biocompatibility tests. An analysis of the current ISO 10993-1 standards was completed to ensure that the existing tests continue to meet the requirements of the current ISO standards. The final reports of the biocompatibility testing are provided in this section (Appendix 15-A). The FDA Standards Data Reports (Form FDA 3654) are included in Appendix 9-A (Section 9).

Table 15-2. Summary of Biocompatibility Tests

Test	Test Method/Model	Results
Cytotoxicity	Agarose Overlay, ISO 10993-5	Non-cytotoxic; No evidence of causing any cell lysis or toxicity.
Sensitization	Guinea Pig Maximization, ISO 10993-10	No evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig test.
Intracutaneous Reactivity	Intracutaneous Study in Rabbits, ISO 10993-10	Under the conditions of the study, there was no irritation or toxicity from the extract injected intracutaneously into rabbits.
Acute Systemic Toxicity	Acute Systemic Toxicity in Mice, ISO 10993-11	No mortality or evidence of systemic toxicity
Genotoxicity	Bacterial Reverse Mutation Study, ISO 10993-3	Non-mutagenic to <i>Salmonella typhimurium</i> and to <i>Escherichia coli</i> strain WP2uvra
	Mouse Lymphoma Assay, ISO 10993-3:2003 or ISO 10993-12:2007*	None of the test article treatments induced substantial increases in the number of revertant colonies. Based on the criteria and conditions of the study protocol, the test article is considered non-mutagenic
	In Vivo Mouse Micronucleus Assay, ISO 10993-3:2003 or ISO 10993-12:2007*	None of the mice treated with the test article preparations exhibited overt signs of toxicity either immediately post-treatment or during the induction period. The levels of micronucleated cells were within normal negative ranges. Based on the criteria and conditions of the study protocol, the test article is considered non-mutagenic.
Pyrogenicity	Rabbit Pyrogen study- USP <151>	Non-pyrogenic
Muscle Implantation	Muscle Implantation Study in Rabbits, 1 Weeks, ISO 10993-6	The macroscopic reaction was not significant compared with the USP negative control implant material. Microscopically, the test article was classified as a nonirritant as compared to the USP negative control article.
Subacute/ Subchronic/ Chronic Toxicity	Subcutaneous implantation study in rat.	Minimum tissue reaction up to 24 weeks of implantation and no adverse tissue reaction to the host.

(b)(4) Trade Secret Process

16. SOFTWARE

The device does not contain software, therefore this section is not applicable to this submission.

17. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The device does not include an electronic component, therefore this section is not applicable to this submission.

18. PERFORMANCE TESTING - BENCH

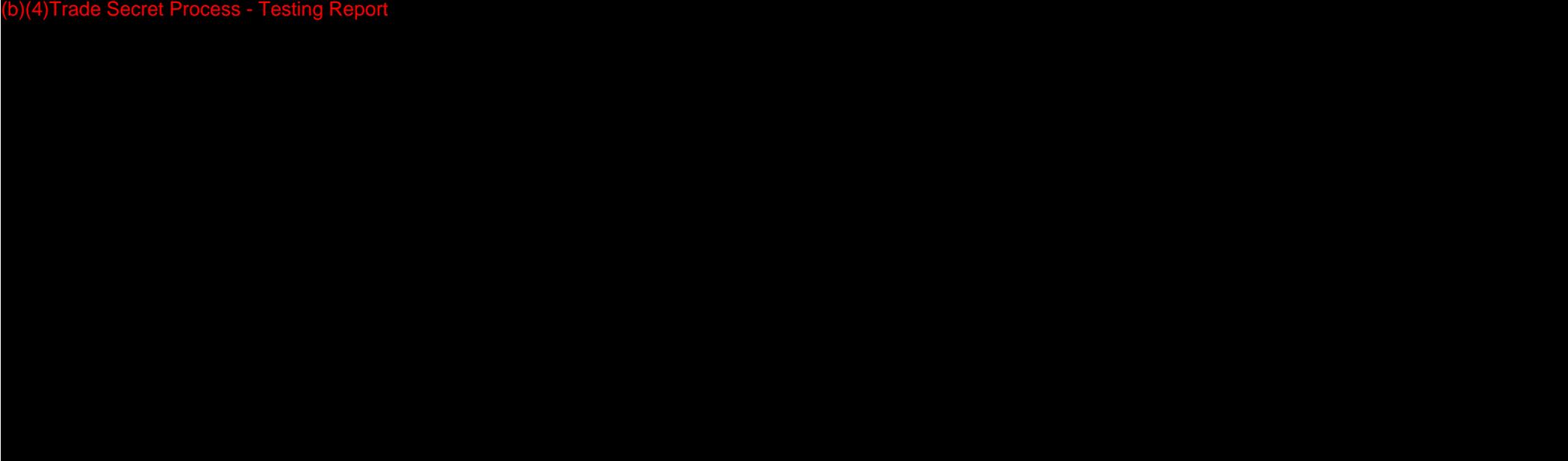
18.1 Design Verification

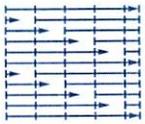
The design was verified by comparing the Design Input (Product Design Requirements, Section 11.4) and the Design Output. Table 18-1 shows the Design Verification Matrix for the product using the 4 mm diameter data to represent the design verification. Data from other sizes (e.g. 2 mm and 6 mm) are presented in the Design Verification Report in Appendix 18-A. All output results were within the specifications originally set for the design input requirements.

Table 18-1. Design Verification Matrix

Parameter	Product Specification	Design Output
(b)(4)Trade Secret Process		
Material Composition (b)(4)Trade Secret Process		
Chemical and Physical Properties (b)(4)Trade Secret Process		

Parameter	Product Specification	Design Output
(b)(4)Trade Secret Process		
Biological Properties		
Biocompatibility	Biocompatible (Pass FDA G95-1 and ISO 10993)	<p>(b)(4)Trade Secret Process</p> <p>passed all tests (Section 15)</p> <ul style="list-style-type: none"> • Cytotoxicity • Sensitization • Intracutaneous reactivity • Acute systemic toxicity • Genotoxicity • Pyrogenicity • Implantation • Subacute/Subchronic/Chronic toxicity <p>(b)(4)Trade Secret Process</p>
Pyrogenicity	Non-pyrogenic (≤ 0.5 EU/ml) as measured by bacterial endotoxin test USP <51>	Non-pyrogenic (b)(4)Trade Secret
Sterility	Sterile, SAL 10^{-6}	Terminal sterilization by gamma irradiation. Sterilization validation. (Section 14.1)
Stability		
Shelf-Life	(b)(4)T	(b)(4)Trade Secret
Packaging		
Packaging	Double peel package	Double peel blister with Tyvek lid





Collagen Matrix, Inc.

15 Thornton Road, Oakland, NJ 07436 • Tel: 201-405-1477 • Fax: 201-405-1355

K131541/S001

July 9, 2013

VIA FEDERAL EXPRESS

Document Mail Center WO66-G609
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
Attn: Xiaolin Zheng

FDA CDRH DMC
JUL 11 2013
Received

Re: 510(k) Premarket Notification (Traditional)
Flexible Collagen Nerve Cuff
K131541 / S001
Additional Information

Dear Ms. Zheng:

This submission is in response to the FDA's Refuse to Accept notification received on June 11, 2013.

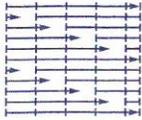
The requested information is provided in the enclosed document. We hope that this information adequately addresses the issues to allow for acceptance and further review of the 510(k) submission.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Peggy Hansen, RAC
Vice President, Clinical, Regulatory, Quality Assurance, and Marketing

Enclosures (submitted in duplicate – 1 paper copy and 1 electronic copy)



Collagen Matrix, Inc.

15 Thornton Road, Oakland, NJ 07436 • Tel: 201-405-1477 • Fax: 201-405-1355

July 9, 2013

VIA FEDERAL EXPRESS

Document Mail Center WO66-G609
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
Attn: Xiaolin Zheng

Re: 510(k) Premarket Notification (Traditional)
Flexible Collagen Nerve Cuff
K131541 / S001
Additional Information

Dear Ms. Zheng:

This submission is in response to the FDA's Refuse to Accept notification received on June 11, 2013.

The requested information is provided in the enclosed document. We hope that this information adequately addresses the issues to allow for acceptance and further review of the 510(k) submission.

If you have any questions, please do not hesitate to contact me.

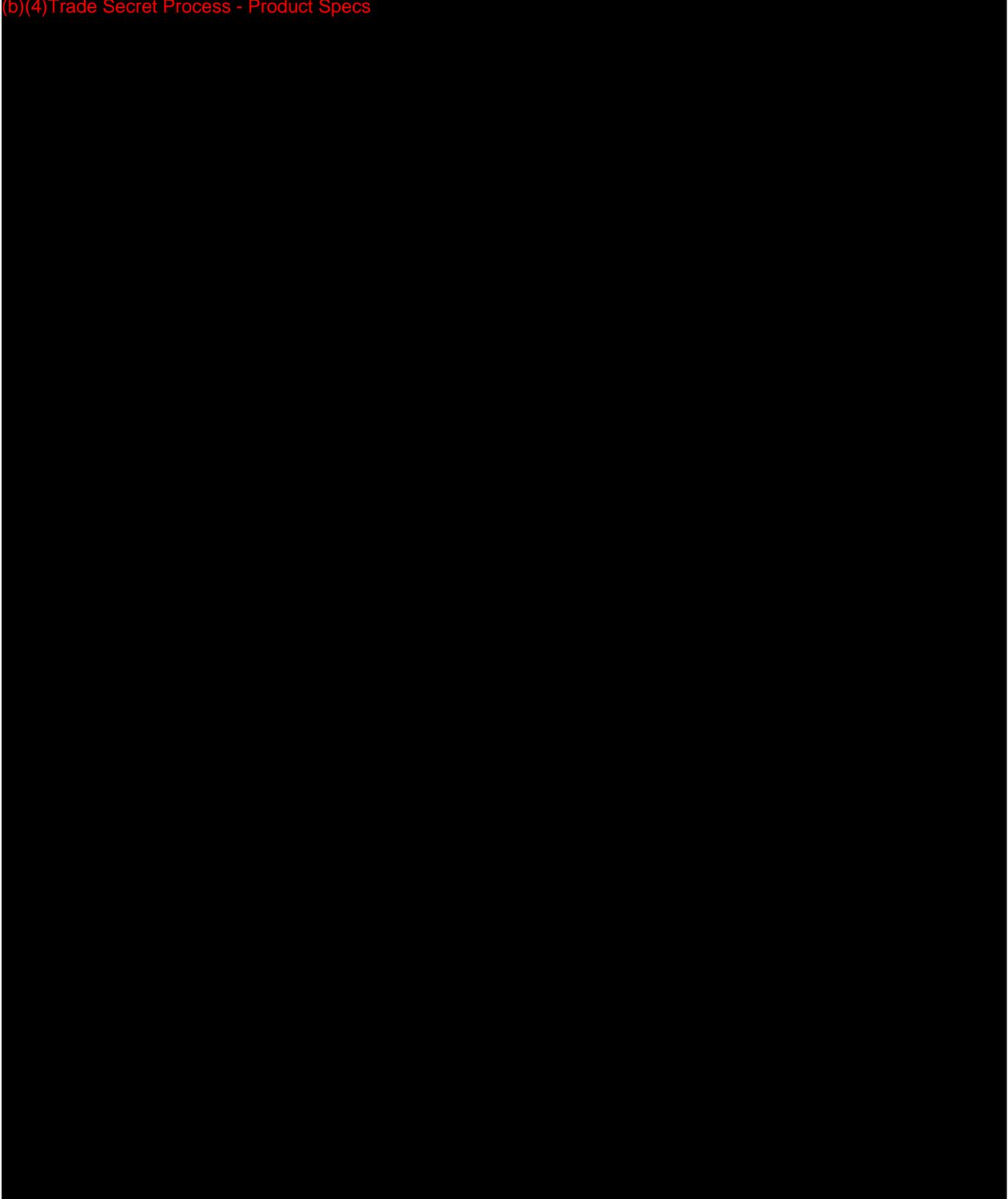
Sincerely,

Peggy Hansen, RAC
Vice President, Clinical, Regulatory, Quality Assurance, and Marketing

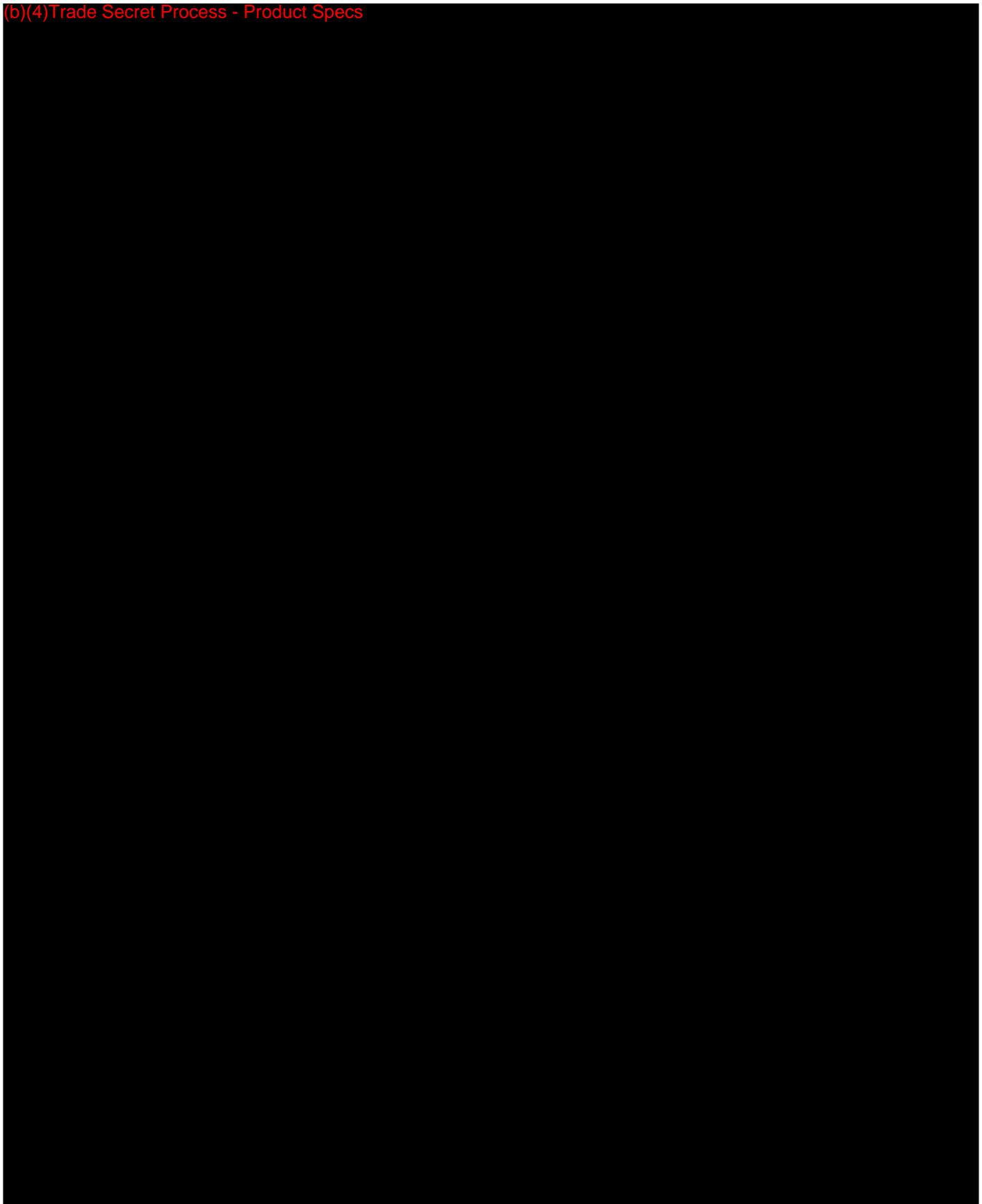
Enclosures (submitted in duplicate – 1 paper copy and 1 electronic copy)

COLLAGEN MATRIX, INC.

(b)(4) Trade Secret Process - Product Specs



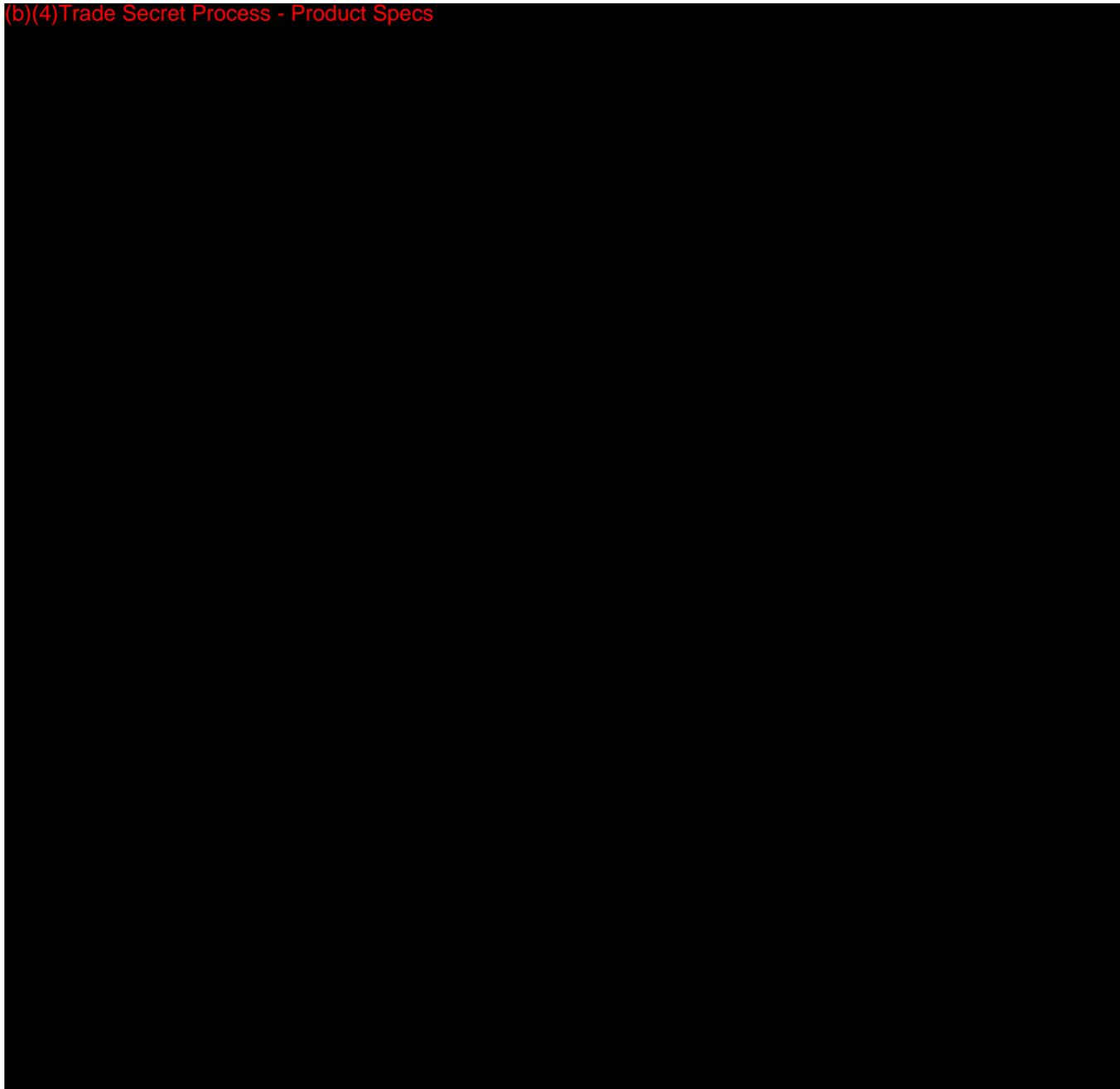
(b)(4)Trade Secret Process - Product Specs



(b)(4)Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



510(k) SUMMARY

1. Applicant Information

Applicant Name: Collagen Matrix, Inc.
Address: 15 Thornton Road
Oakland, New Jersey 07436
Telephone: (201) 405-1477
Fax: (201) 405-1355
Contact Person: Peggy Hansen, RAC
VP, Clinical, Regulatory, QA, and Marketing
Date Prepared: July 9, 2013

2. Name of the Device

Device Common Name: Nerve Cuff
Device Trade Name: Flexible Collagen Nerve Cuff
Device Classification Name: Nerve cuff
882.5275
JXI
Class II

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): Collagen Nerve Cuff
K012814

Silastic® Nerve Cuff
Pre-amendment Device

4. Description of the Device

Flexible Collagen Nerve Cuff is a resorbable, flexible type I collagen tubular matrix that provides both an encasement for peripheral nerve injuries as well as protection of the neural environment. Flexible Collagen Nerve Cuff is designed to be an interface between the nerve and the surrounding tissue (e.g., to prevent ingrowth of scar tissue). When placed at the terminal end of a nerve, the Flexible Collagen Nerve Cuff is designed to prevent formation of neuroma. When hydrated, Flexible Collagen Nerve Cuff is a flexible collagen conduit where the crimped walls provide a kink-resistant property to the tube. It is supplied sterile, non-pyrogenic, in various sizes and for single use only.

5. Intended Use

Flexible Collagen Nerve Cuff is used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.

6. Summary/Comparison of Technical Characteristics

Flexible Collagen Nerve Cuff is the identical product to the Company's currently marketed Neuroflex™ Collagen Nerve Cuff. The 510(k) premarket notification was submitted for expanded indications.

Parameter	Flexible Collagen Nerve Cuff (This submission)	Collagen Nerve Cuff K012814	Silastic® Nerve Cuff
Indications for Use	Intended for use in the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.	Intended for use in the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.	Intended to be used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).
Material	Type I collagen	Type I collagen	Silicone
Source	Bovine tendon	Bovine tendon	Synthetic
Form	Tubular matrix	Tubular matrix	Tubular matrix
Color	White to off-white	White to off-white	Opaque
Sizes	2 mm ID x 2.5 cm length 2.5 mm IDx 2.5 cm length 3 mm ID x 2.5 cm length 4 mm ID x 2.5 cm length 5 mm ID x 2.5 cm length 6 mm ID x 2.5 cm length	2 mm ID x 2.5 cm length 2.5 mm IDx 2.5 cm length 3 mm ID x 2.5 cm length 4 mm ID x 2.5 cm length 5 mm ID x 2.5 cm length 6 mm ID x 2.5 cm length	3.3 mm ID x 1.0 cm length 4.1 mm ID x 1.0 cm length 4.8 mm ID x 1.0 cm length 5.3 mm ID x 1.3 cm length 6.1 mm ID x 1.3 cm length 7.1 mm ID x 1.3 cm length 7.9 mm ID x 1.5 cm length 8.6 mm ID x 1.5 cm length 9.9 mm ID x 1.5 cm length 10.7 mm IDx 1.5 cm length 11.7 mm IDx 1.8 cm length 13.7 mm IDx 1.8 cm length
Mechanical Strength	Can be sutured	Can be sutured	Can be sutured
Resorbable	Yes	Yes	No
Crosslinked	Yes	Yes	No
Porosity/ Permeability	Semi-permeable. Permeable to nutrients and macromolecules	Semi-permeable Permeable to nutrients and macromolecules	Non-permeable
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Sterility	Sterile, SAL 10 ⁻⁶ Gamma irradiation	Sterile, SAL 10 ⁻⁶ Gamma irradiation	Sterile
Pyrogenicity	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml	Unknown
Single Use/Reuse	Single use only	Single use only	Single use only
Packaging	Double peel package	Double peel package	Sterile vials of distilled water

Nonclinical Tests Submitted

The substantial equivalence of the Flexible Collagen Nerve Cuff and its predicate device was demonstrated based on an evaluation of the expanded indications.

In vitro characterization studies included evaluation of physical properties such as suture strength, kink resistance, and an evaluation of physicochemical properties such as product permeability and hydrothermal transition temperature. The characterization test results of the subject device were equivalent to those of the predicate device, given that there has been no change to the device itself.

The Flexible Collagen Nerve Cuff material was evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The representative product passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices.

Viral inactivation studies were performed to ensure the viral safety of the product.

Clinical Test Submitted

A clinical study was submitted that evaluated the use of the Flexible Collagen Nerve Cuff in the management of painful neuromas of the foot and ankle. A total of 50 patients underwent excision of painful single or multiple neuromas with the end of the resected nerve sutured into the Flexible Collagen Nerve Cuff subject device. Each patient preoperatively was asked to describe the amount of pain he or she was experiencing on a scale from 1 to 10, with 10 indicating the most severe pain. In the telephone interview conducted during this study, the same question was asked of each patient following revision. Patient ages ranged from 16 to 77 years, with a mean of 54 years. In all, 30 right and 20 left sides were operated, and 1 patient had bilateral involvement. Mean follow-up was 36 months (6-55 months). There were a total of 69 nerves that underwent conduit procedures. The results showed an 85% success rate of reducing pain for the treatment of neuroma in the foot and 77% (weighted average) success rate of reducing pain in the treatment of neuroma in foot and ankle combined.

Conclusions Drawn from Non-clinical and Clinical Studies

The results of the material evaluation, *in vitro* product characterization studies, biocompatibility studies, animal and clinical studies show that the Flexible Collagen Nerve Cuff is safe and substantially equivalent to the predicate device. The expanded indication for use does not affect the safety and performance of the device.

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).
- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Peggy Hansen	TITLE VP, Clinical, Regulatory, QA, and Marketing
FIRM/ORGANIZATION Collagen Matrix, Inc.	
SIGNATURE 	DATE (mm/dd/yyyy) 07/02/2013

This section applies only to the requirements of the Paperwork Reduction Act of 1995.
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. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
PRAStaff@fda.hhs.gov

"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 number."



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter Collagen Matrix, Inc.		2. Date of the Application/Submission Which This Certification Accompanies 05/24/2013	
3. Address		4. Telephone and Fax Numbers (Include country code if applicable and area code)	
Address 1 (Street address, P.O. box, company name c/o) 15 Thornton Road		(Tel): 201-405-1477	
Address 2 (Apartment, suite, unit, building, floor, etc.)		(Fax): 201-405-1355	
City Oakland	State/Province/Region NJ		
Country USA	ZIP or Postal Code 07436		

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Trade Name: Neuroflex(TM) Flexible Collagen Nerve Cuff

Common or Usual Name(s): Nerve Cuff, Nerve Conduit

Regulation Number: 882.5275
Product Code: JXI
Device Class: Class II

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

- IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/ Other Number
(If number previously assigned)

510(k) Number K131541.

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes (See instructions for additional information and explanation)

- A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply because the application/submission which this certification accompanies does not reference any clinical trial.
- B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act do not apply to any clinical trial referenced in the application/submission which this certification accompanies.
- C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION (Continued)

10. If you checked box C, in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act, referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s): _____

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name Peggy Hansen	Title VP, Clinical, Regulatory, QA, and Marketing
-----------------------------	---

12. Address

Address 1 (Street address, P.O. box, company name c/o) 15 Thornton Road	
Address 2 (Apartment, suite, unit, building, floor, etc.)	
City Oakland	State/Province/Region NJ
Country USA	ZIP or Postal Code 07436

13. Telephone and Fax Numbers

(Include country code if applicable and area code)

(Tel): 201-405-1477

(Fax): 201-405-1355

14. Date of Certification

07/02/2013

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative (Sign)



Sign

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

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 Paperwork Reduction Act (PRA) Staff
 PRAStaff@fda.hhs.gov

"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 number."

Table 12-1A. Substantial Equivalence Comparison Chart with Comparative Data*

Parameter	Flexible Collagen Nerve Cuff (This submission)	Collagen Nerve Cuff K012814	Silastic® Nerve Cuff Pre-amendment
Indications for Use	Intended for use in the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.	Intended for use in the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.	Intended to be used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).
Material	Type I collagen	Type I collagen	Silicone
Source	Bovine tendon	Bovine tendon	Synthetic
Form	Tubular matrix	Tubular matrix	Tubular matrix
Color	White to off-white	White to off-white	Opaque
Sizes	2 mm ID x 2.5 cm length 2.5 mm ID x 2.5 cm length 3 mm ID x 2.5 cm length 4 mm ID x 2.5 cm length 5 mm ID x 2.5 cm length 6 mm ID x 2.5 cm length	2 mm ID x 2.5 cm length 2.5 mm ID x 2.5 cm length 3 mm ID x 2.5 cm length 4 mm ID x 2.5 cm length 5 mm ID x 2.5 cm length 6 mm ID x 2.5 cm length	3.3 mm ID x 1.0 cm length 4.1 mm ID x 1.0 cm length 4.8 mm ID x 1.0 cm length 5.3 mm ID x 1.3 cm length 6.1 mm ID x 1.3 cm length 7.1 mm ID x 1.3 cm length 7.9 mm ID x 1.5 cm length 8.6 mm ID x 1.5 cm length 9.9 mm ID x 1.5 cm length 10.7 mm IDx 1.5 cm length 11.7 mm IDx 1.8 cm length 13.7 mm IDx 1.8 cm length

(b)(4)Trade Secret Process

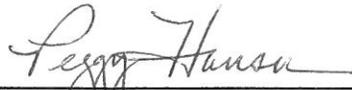
Resorbable	Yes	Yes	No
------------	-----	-----	----

Parameter	Flexible Collagen Nerve Cuff (This submission)	Collagen Nerve Cuff K012814	Silastic® Nerve Cuff Pre-amendment
(b)(4)Trade Secret Process			
Crosslinked	Yes	Yes	No
Method of crosslinking	Formaldehyde	Formaldehyde	Not applicable
Porosity/ Permeability	Semi-permeable. Permeable to nutrients and macromolecules	Semi-permeable Permeable to nutrients and macromolecules	Non-permeable
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Sterility	Sterile, SAL 10 ⁻⁶ Gamma irradiation	Sterile, SAL 10 ⁻⁶ Gamma irradiation	Sterile Method of sterilization unknown
Pyrogenicity	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml	Unknown
Single Use/Reuse	Single use only	Single use only	Single use only
Packaging	Double peel package	Double peel package	Sterile vials with distilled water
Shelf Life	(b)(4)Trade Secret Process		

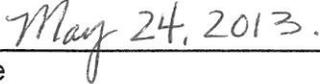
*Based on information from Company brochures, 510(k) Summaries of Safety and Effectiveness, literature, and in-house testing.

6. TRUTHFUL AND ACCURACY STATEMENT

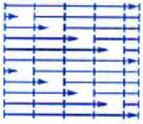
I certify that, in my capacity as Vice President, Clinical, Regulatory, Quality Assurance, and Marketing and Chief Regulatory Officer of Collagen Matrix, Inc., I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification are truthful and accurate and that no material fact has been omitted.



Peggy Hansen, RAC
Vice President, Clinical, Regulatory, Quality Assurance,
and Marketing
Chief Regulatory Officer



Date



Collagen Matrix, Inc.

K131541/S002

15 Thornton Road, Oakland, NJ 07436 • Tel: 201-405-1477 • Fax: 201-405-1355

March 6, 2014

FDA CDRH DMC

MAR 07 2014

Received

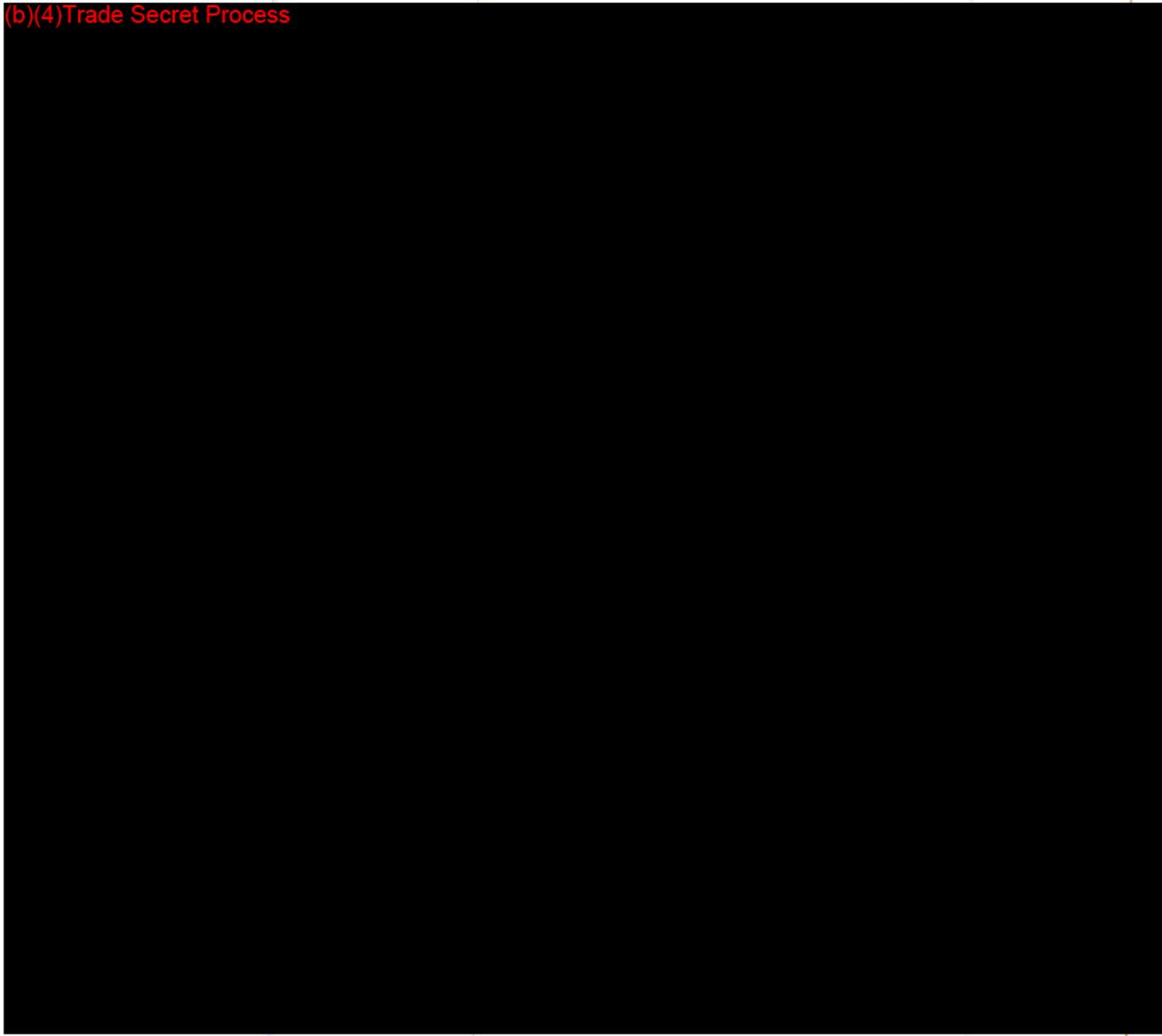
VIA FEDERAL EXPRESS

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

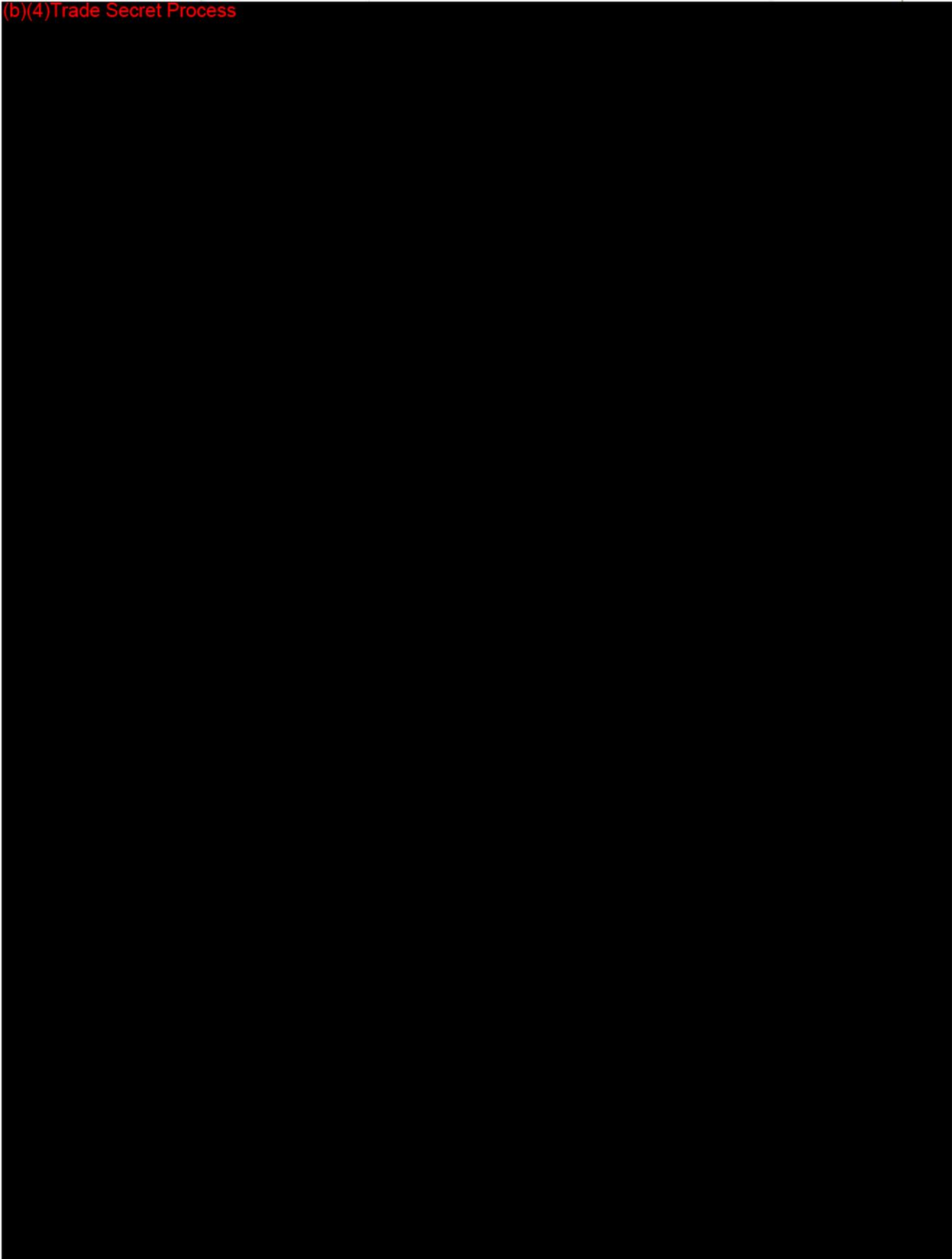
Re: K131541/S002
Flexible Collagen Nerve Cuff

Dear Dr. Zheng:

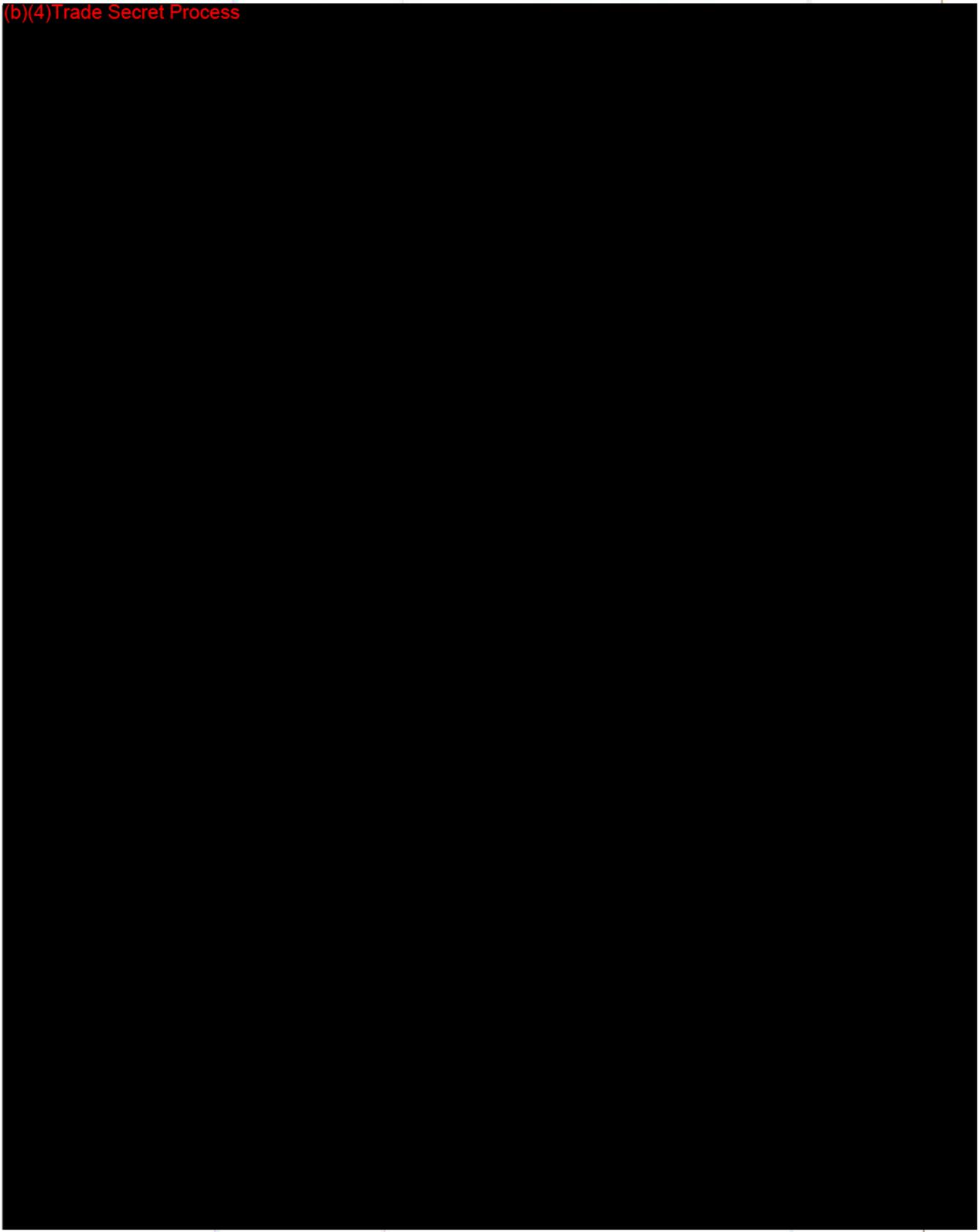
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

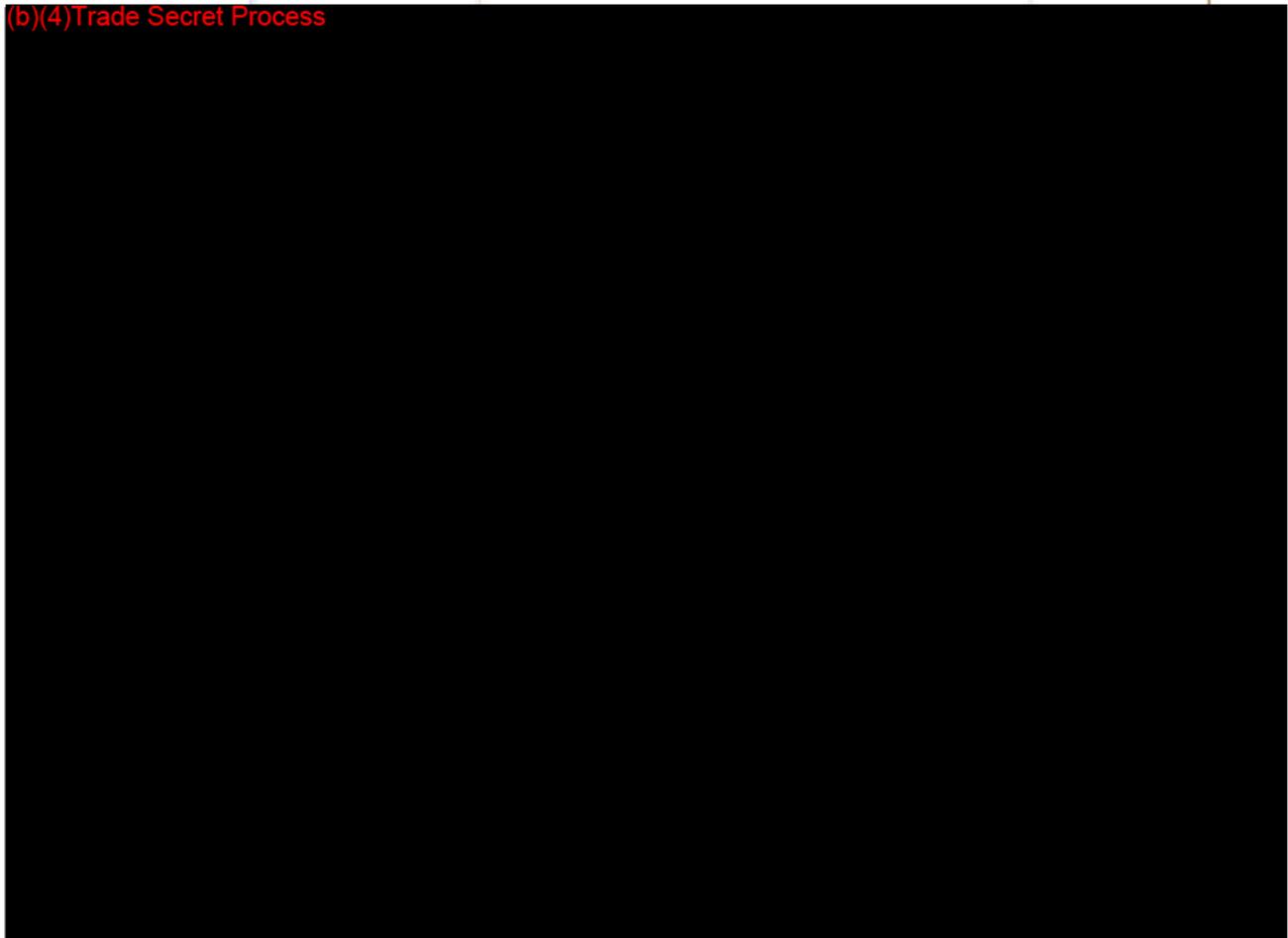


(b)(4)Trade Secret Process



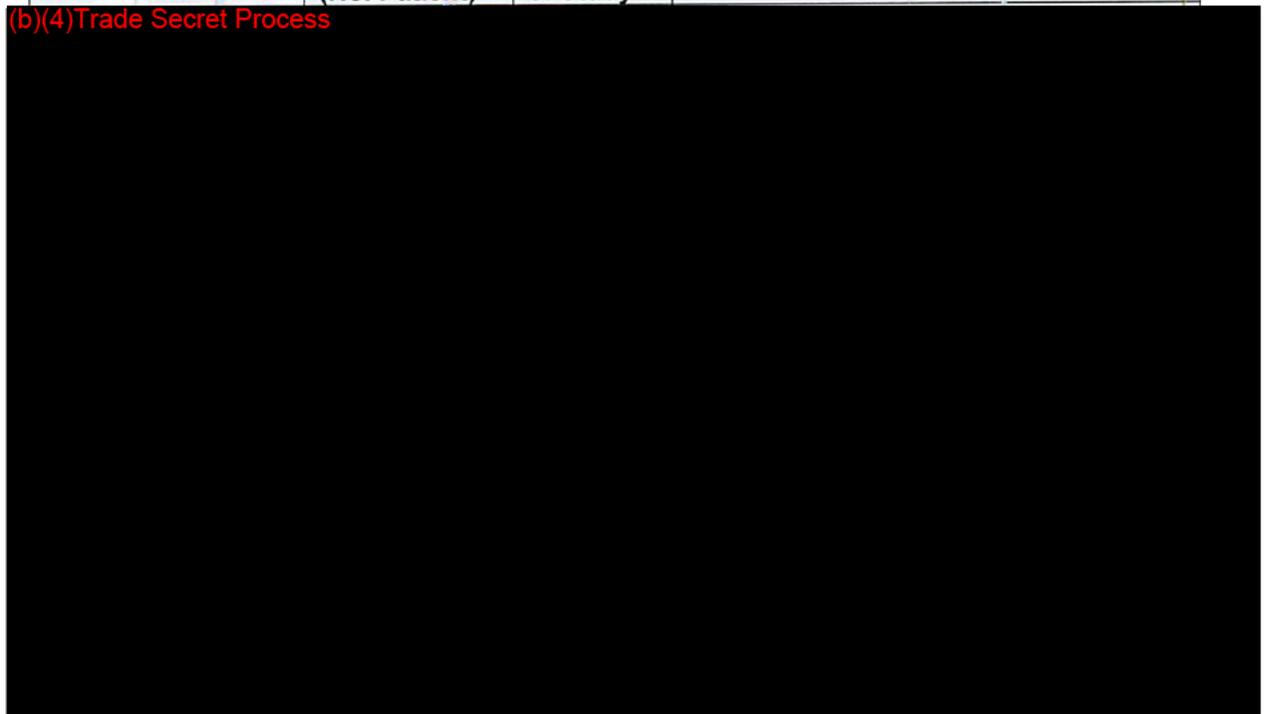
Performance Testing - Clinical

(b)(4)Trade Secret Process



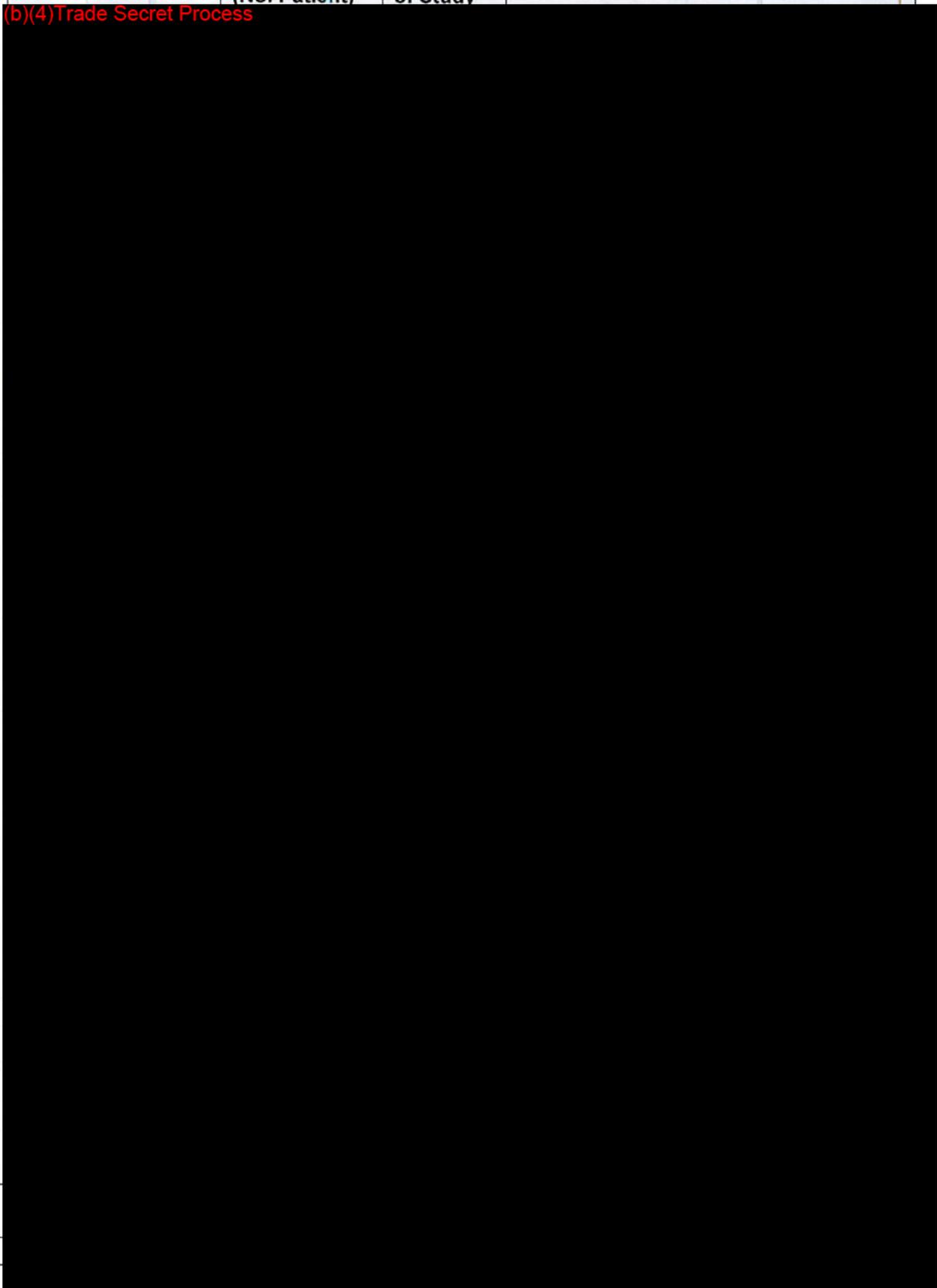
Reference	No. Neuroma (No. Patient)	Duration of Study	Results and Conclusion
-----------	------------------------------	----------------------	------------------------

(b)(4)Trade Secret Process

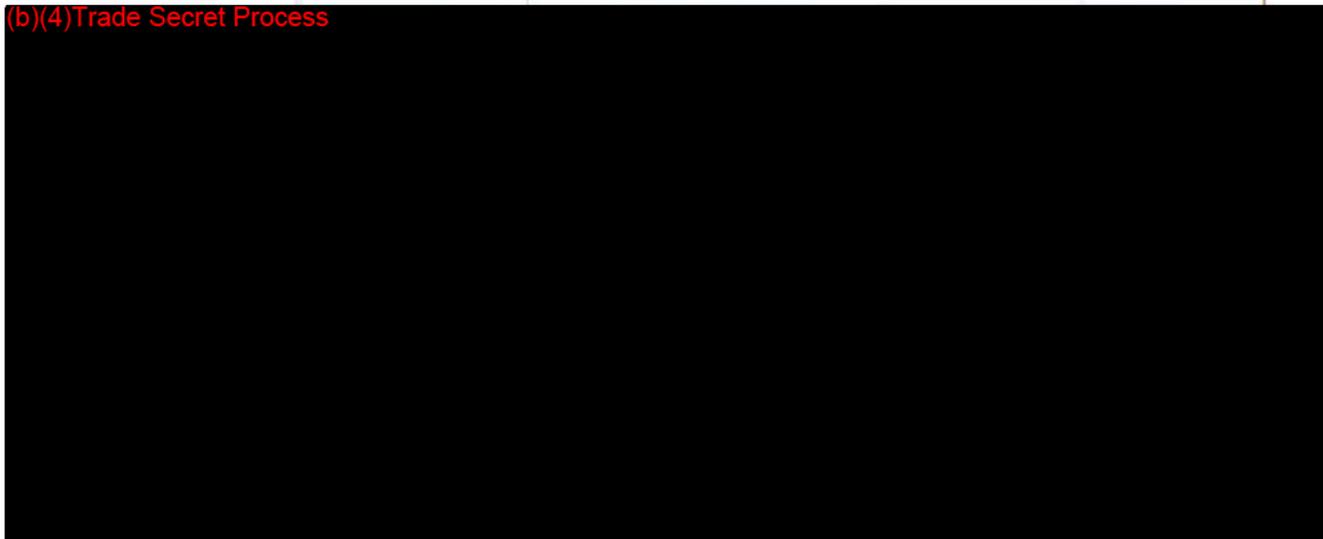


Reference	No. Neuroma (No. Patient)	Duration of Study	Results and Conclusion
-----------	------------------------------	----------------------	------------------------

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



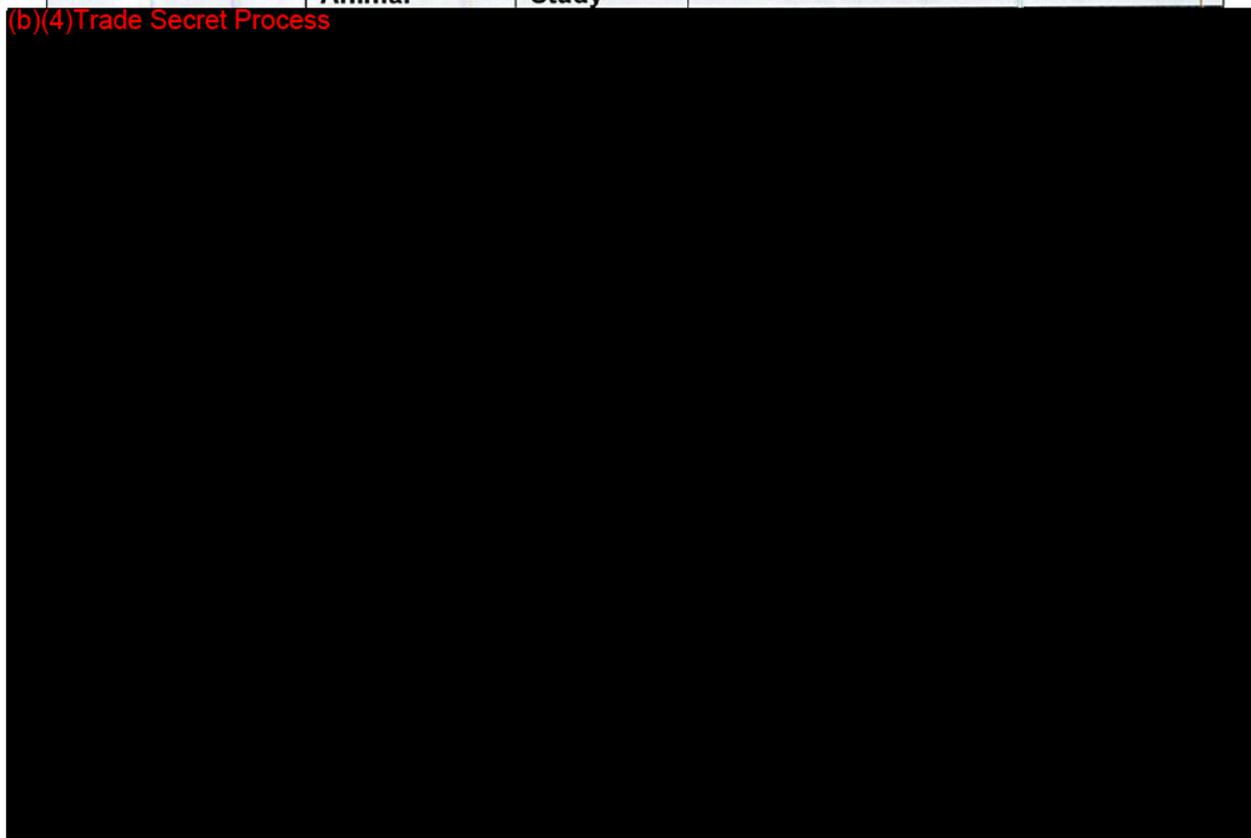
Performance Testing - Animal

(b)(4)Trade Secret Process



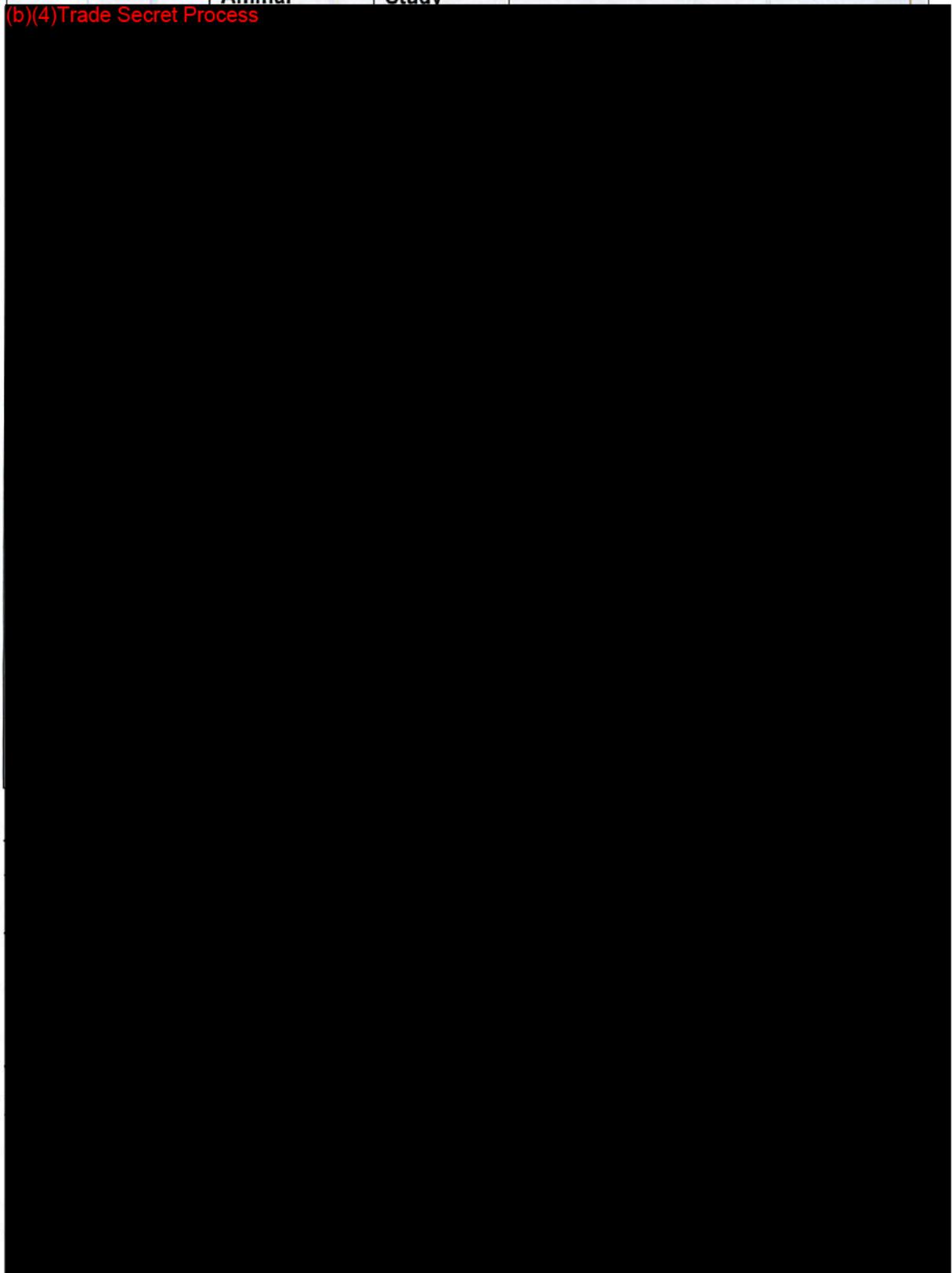
Reference	No. Animal	Duration of Study	Results and Conclusion
-----------	------------	-------------------	------------------------

(b)(4)Trade Secret Process

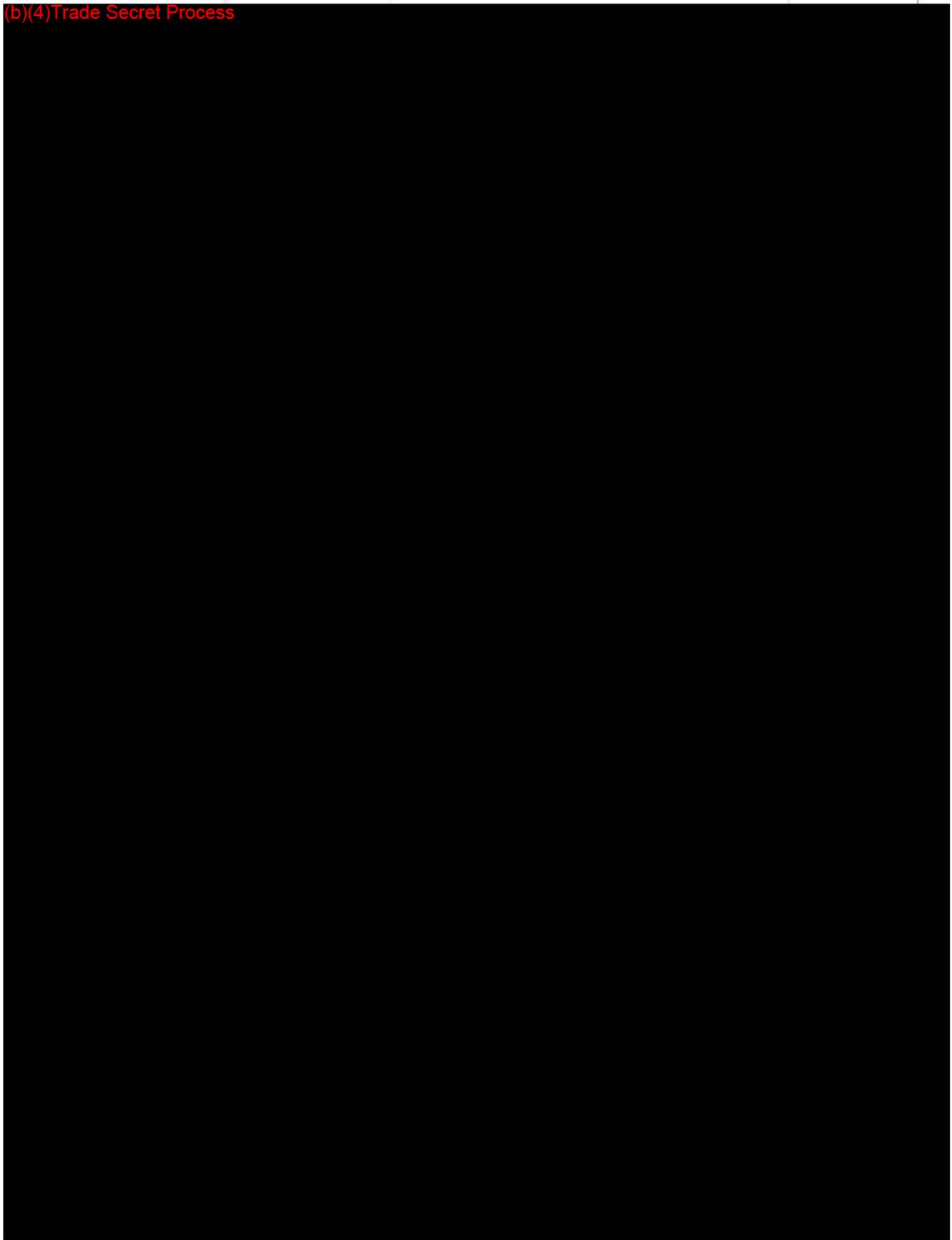


Reference	No. Animal	Duration of Study	Results and Conclusion
-----------	------------	-------------------	------------------------

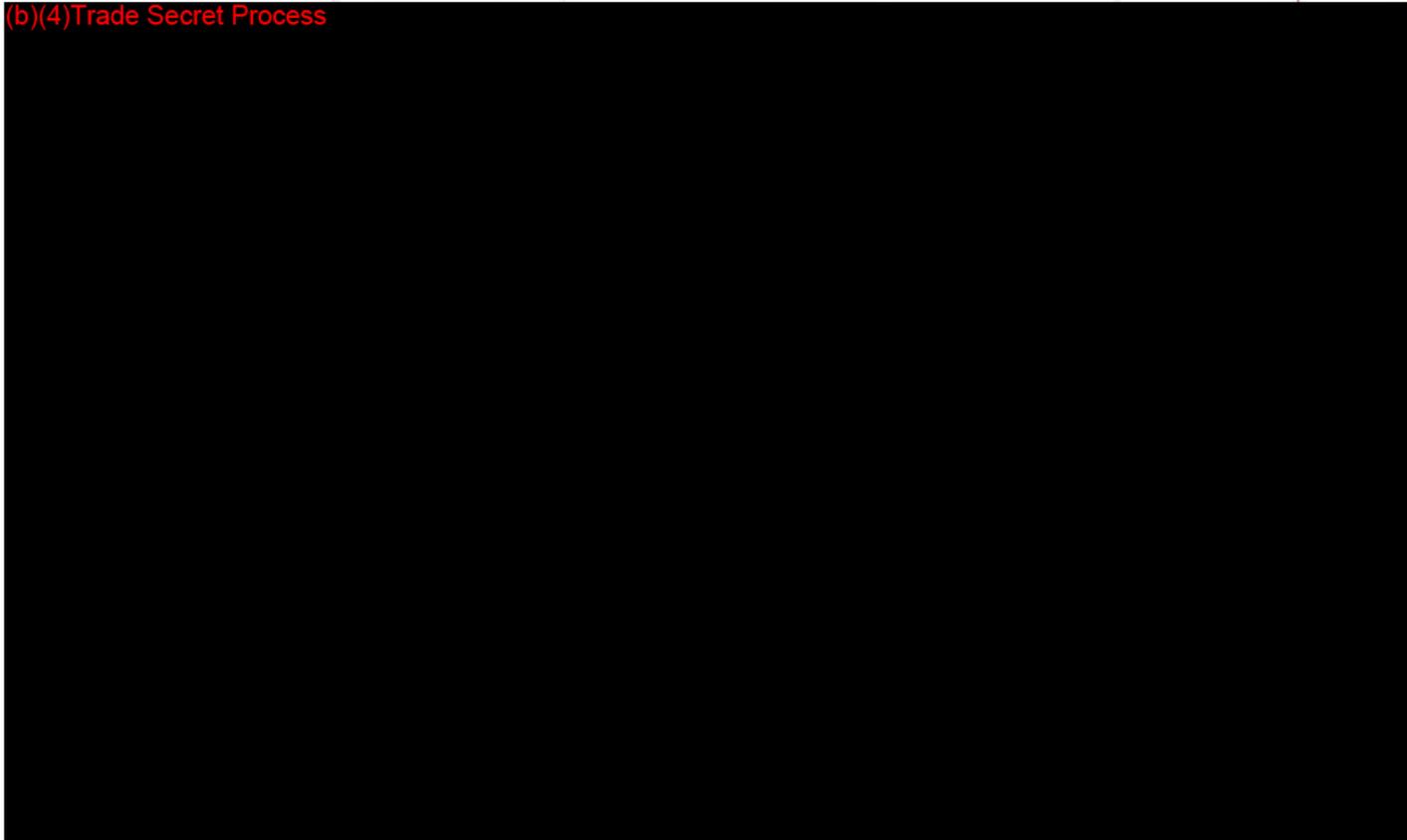
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

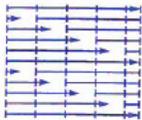


Sincerely,



Peggy Hansen, RAC
Vice President, Clinical, Regulatory, QA, and Marketing
Chief Regulatory Officer

Submitted in duplicate (hard copy and electronic)



Collagen Matrix, Inc.

15 Thornton Road, Oakland, NJ 07436 • Tel: 201-405-1477 • Fax: 201-405-1355

March 6, 2014

VIA FEDERAL EXPRESS

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

Re: K131541/S002
Flexible Collagen Nerve Cuff

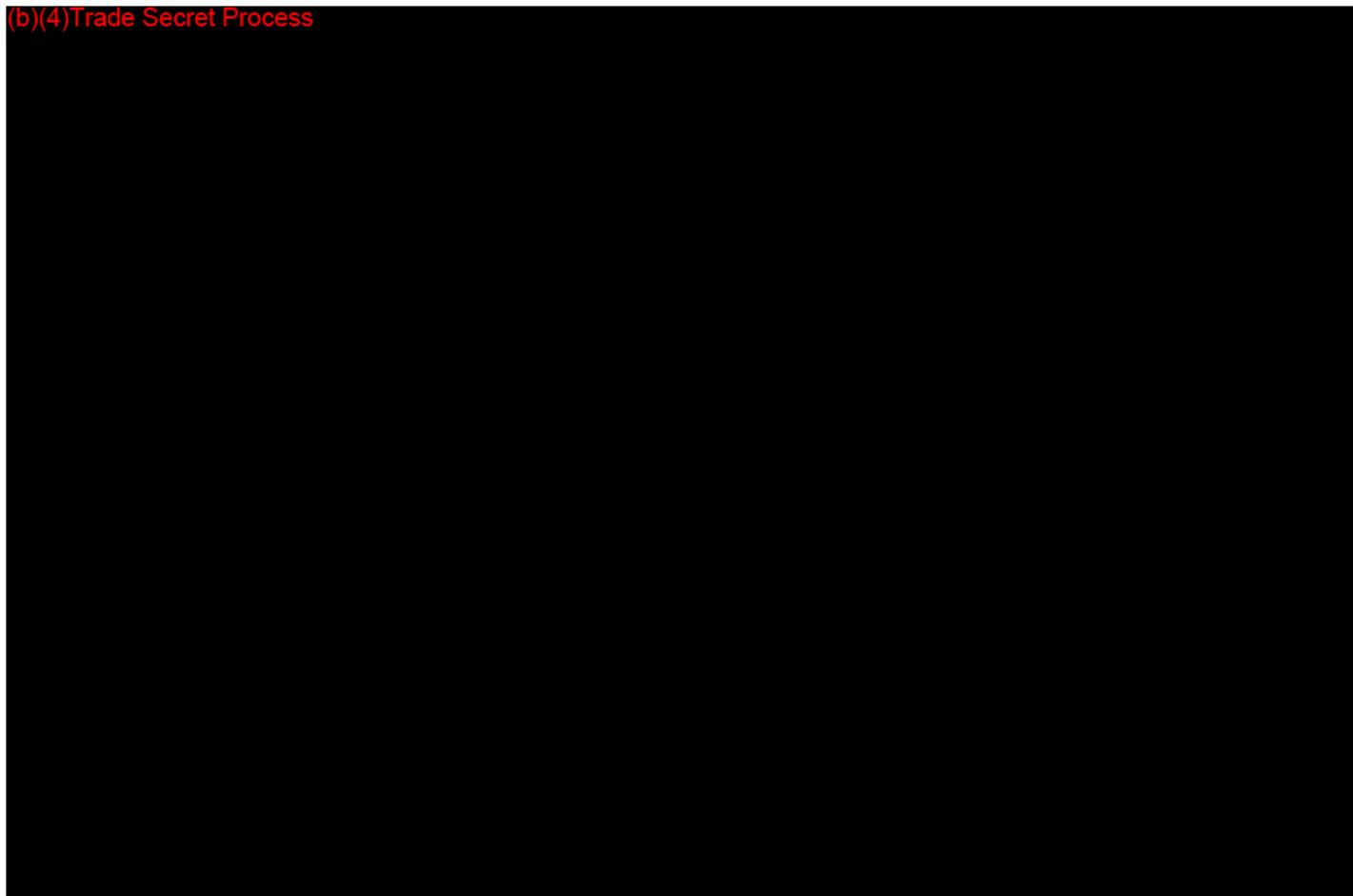
Dear Dr. Zheng:

(b)(4)Trade Secret Process

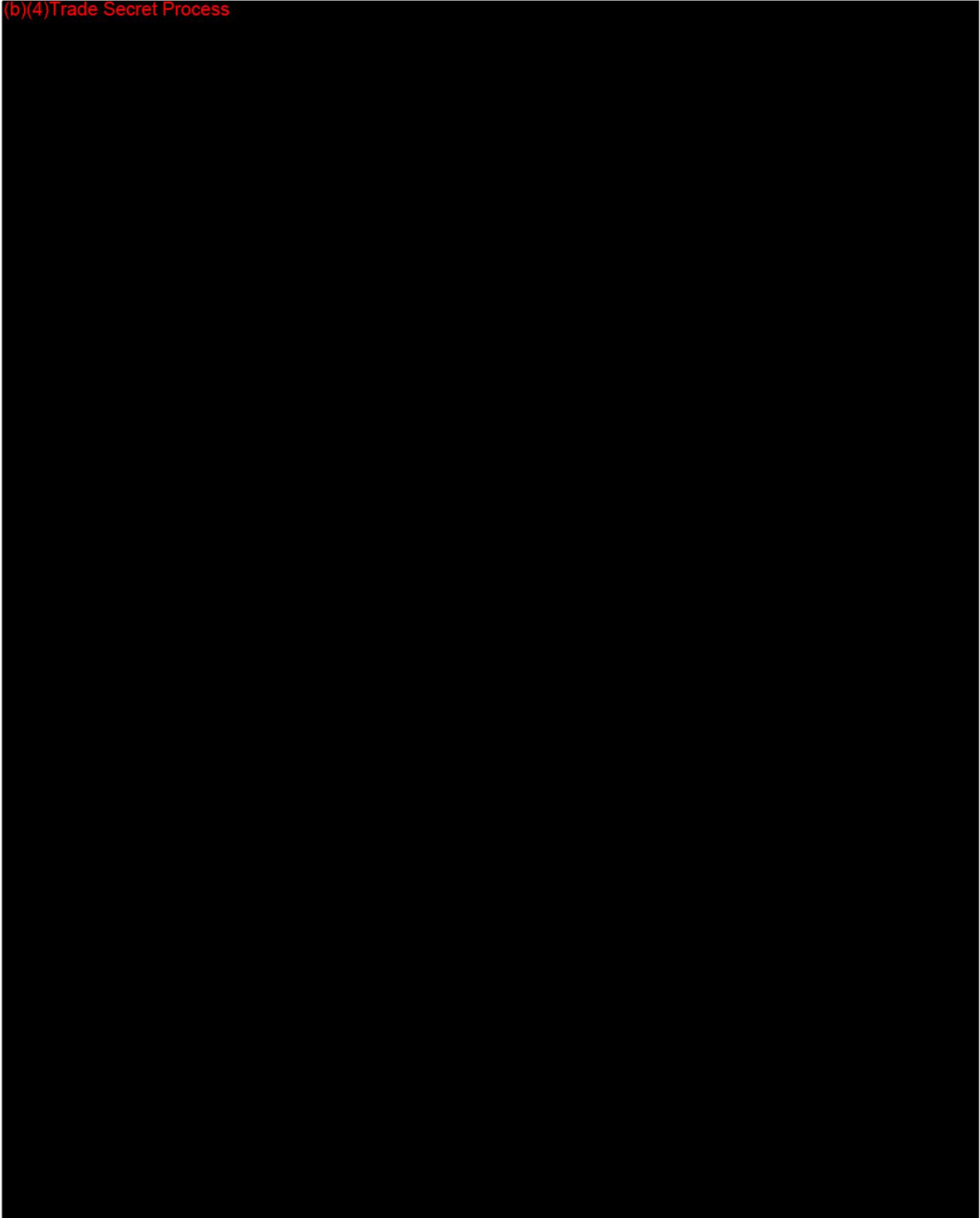
A large black rectangular redaction box covers the majority of the page's content, starting below the salutation and ending above the 'Clinical' heading.

Clinical

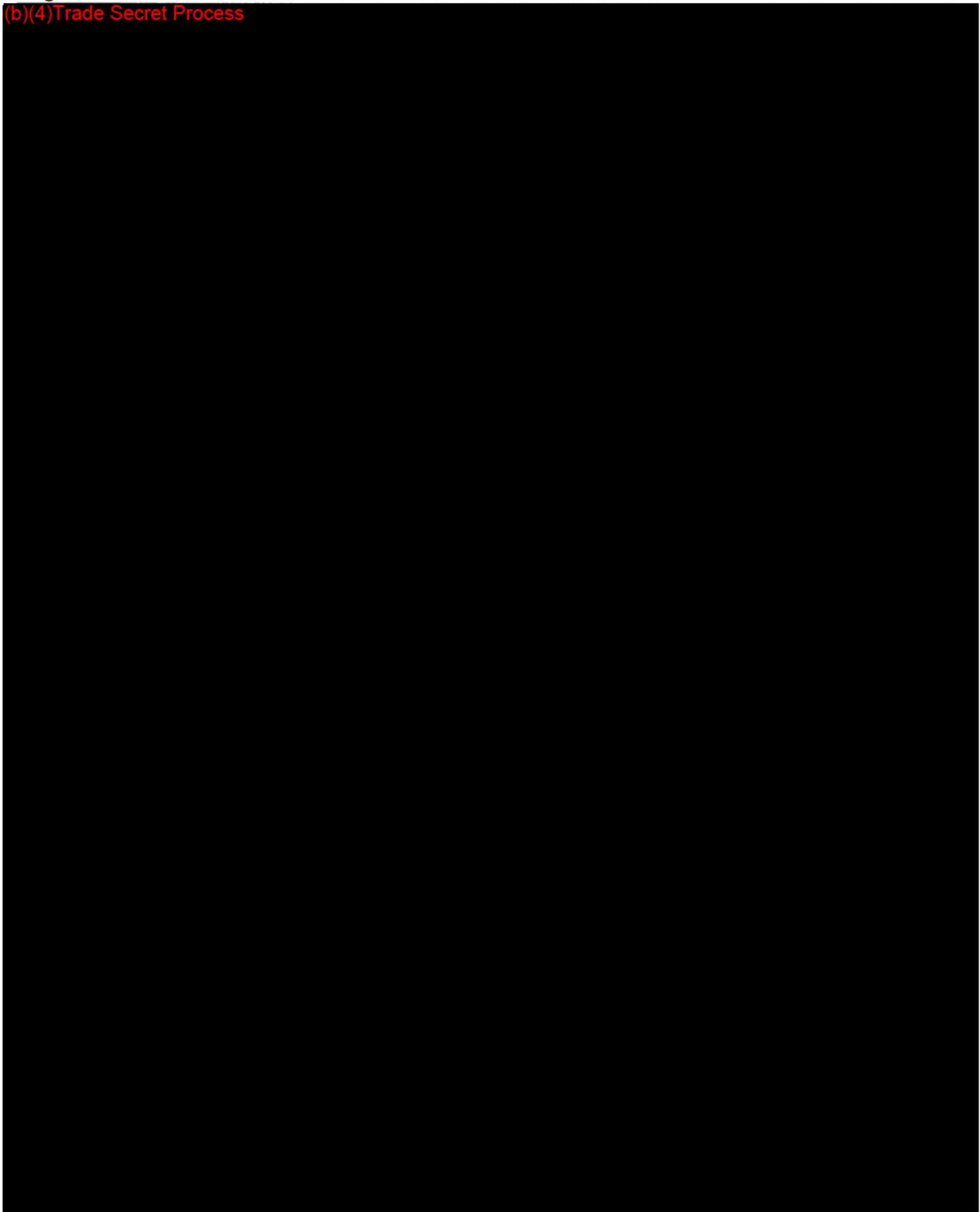
(b)(4)Trade Secret Process

A very large black rectangular redaction box covers the entire bottom half of the page, starting below the 'Clinical' heading and extending to the bottom edge.

(b)(4) Trade Secret Process

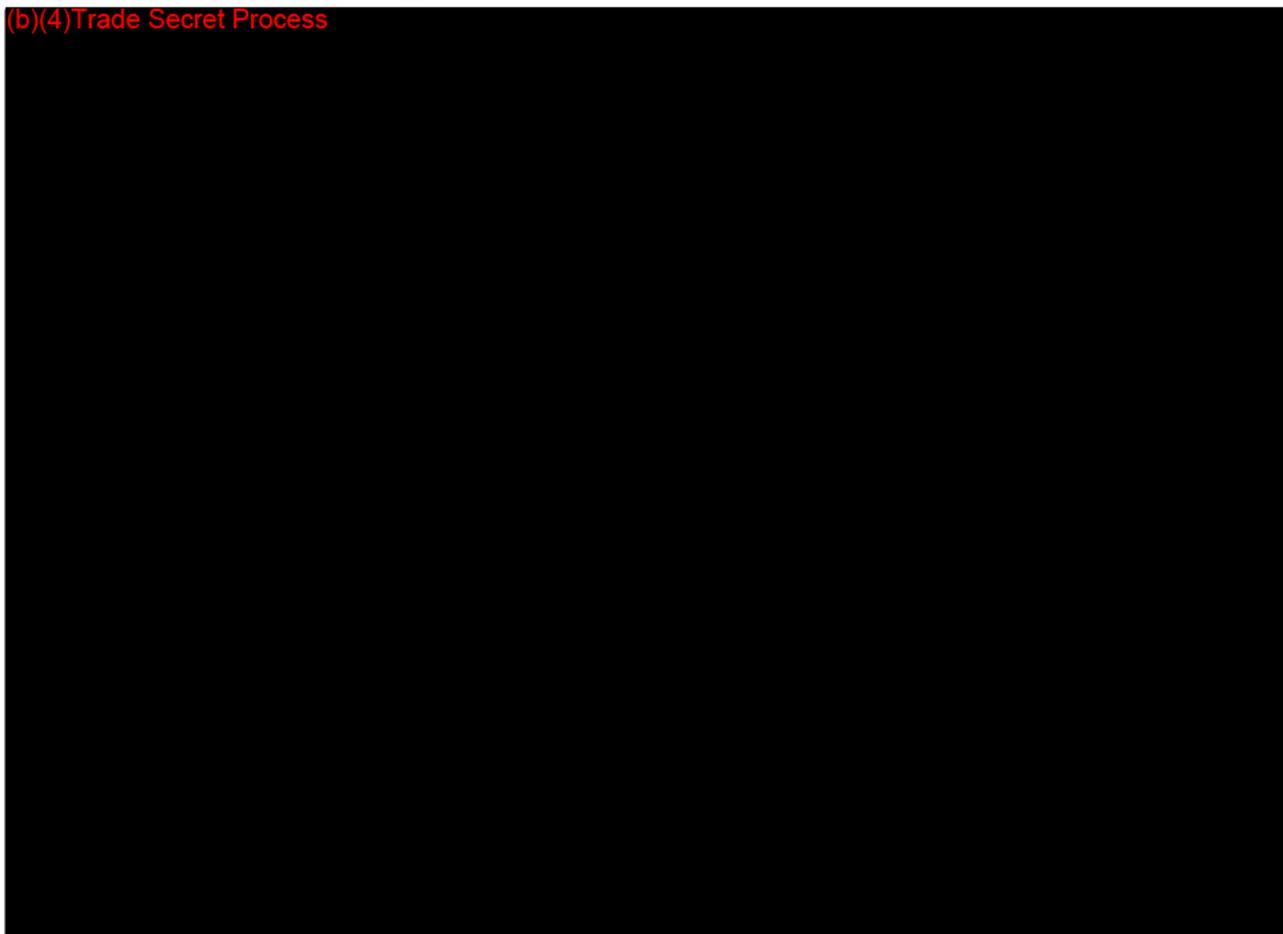


(b)(4)Trade Secret Process



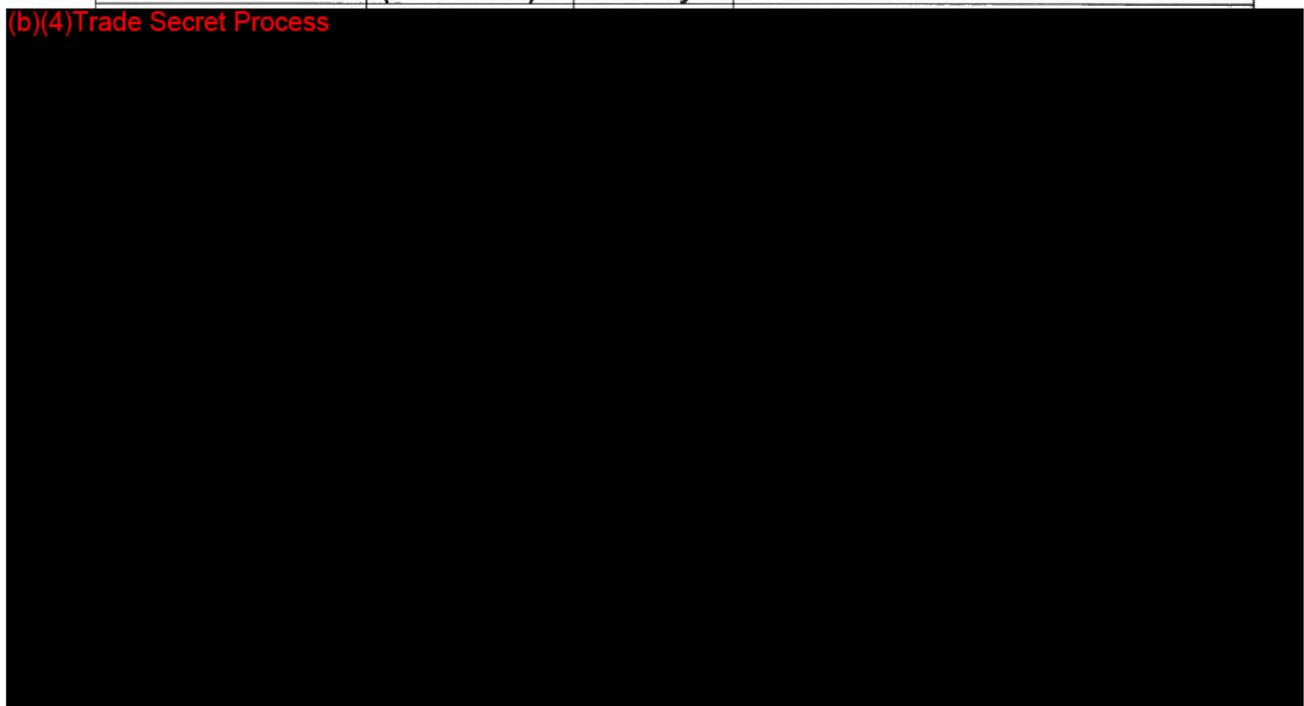
Performance Testing - Clinical

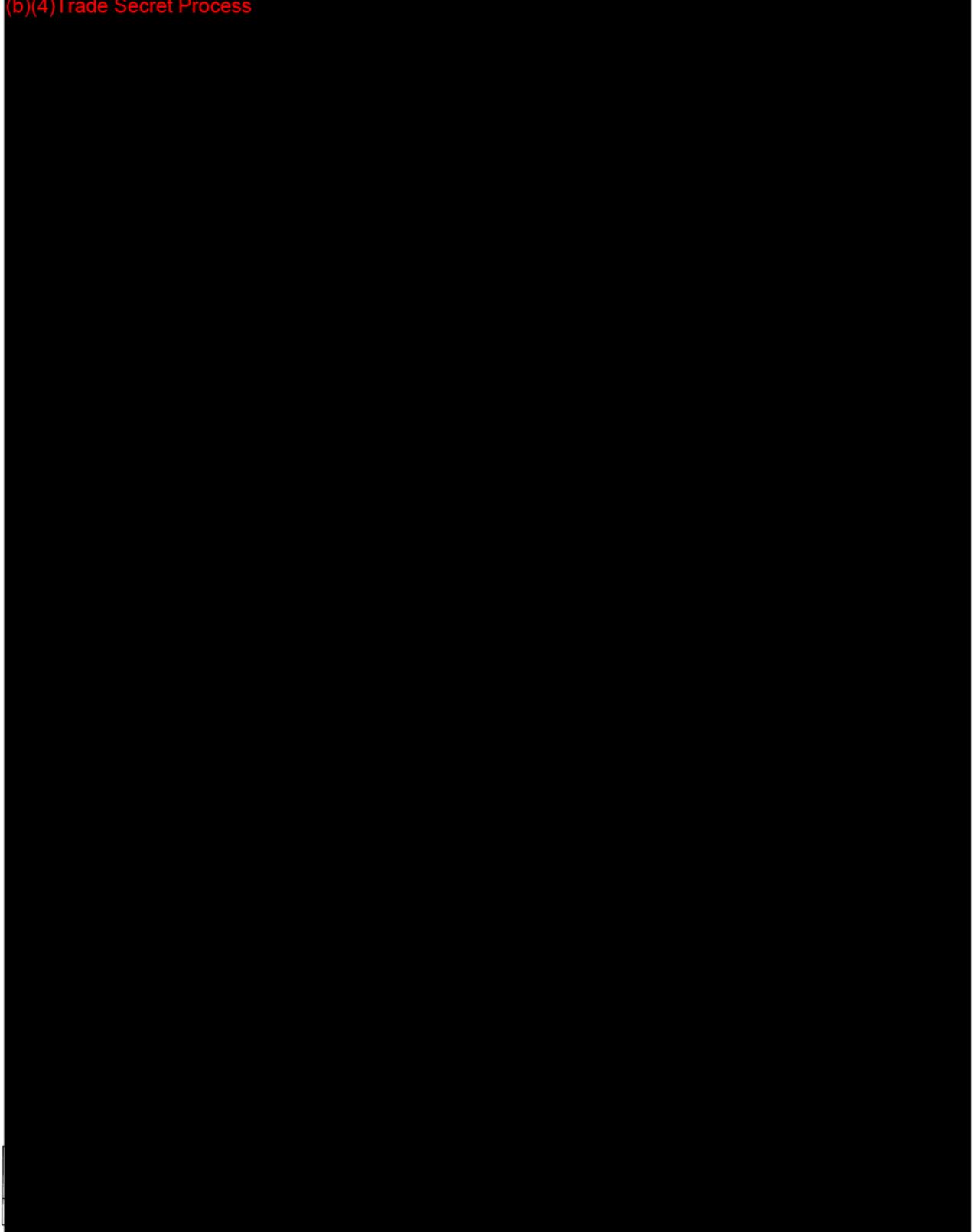
(b)(4) Trade Secret Process



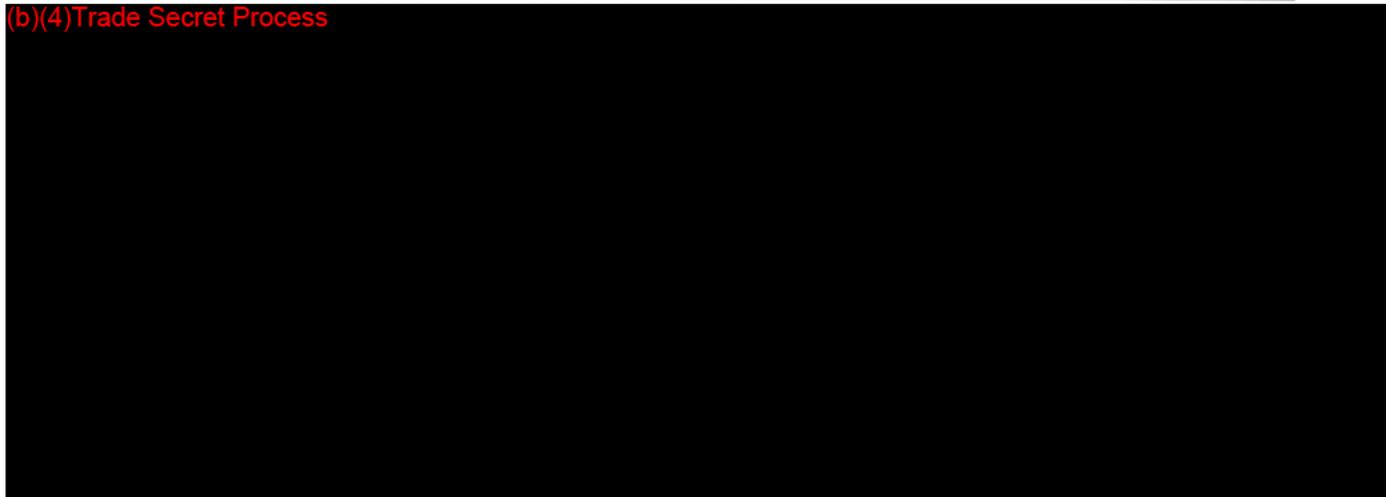
Reference	No. Neuroma (No. Patient)	Duration of Study	Results and Conclusion
-----------	------------------------------	----------------------	------------------------

(b)(4) Trade Secret Process



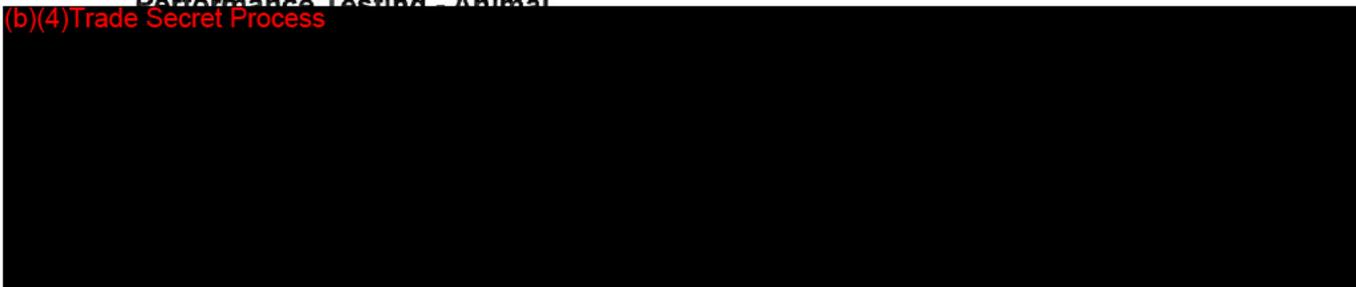
Reference	No. Neuroma (No. Patient)	Duration of Study	Results and Conclusion
(b)(4) Trade Secret Process 			

(b)(4)Trade Secret Process



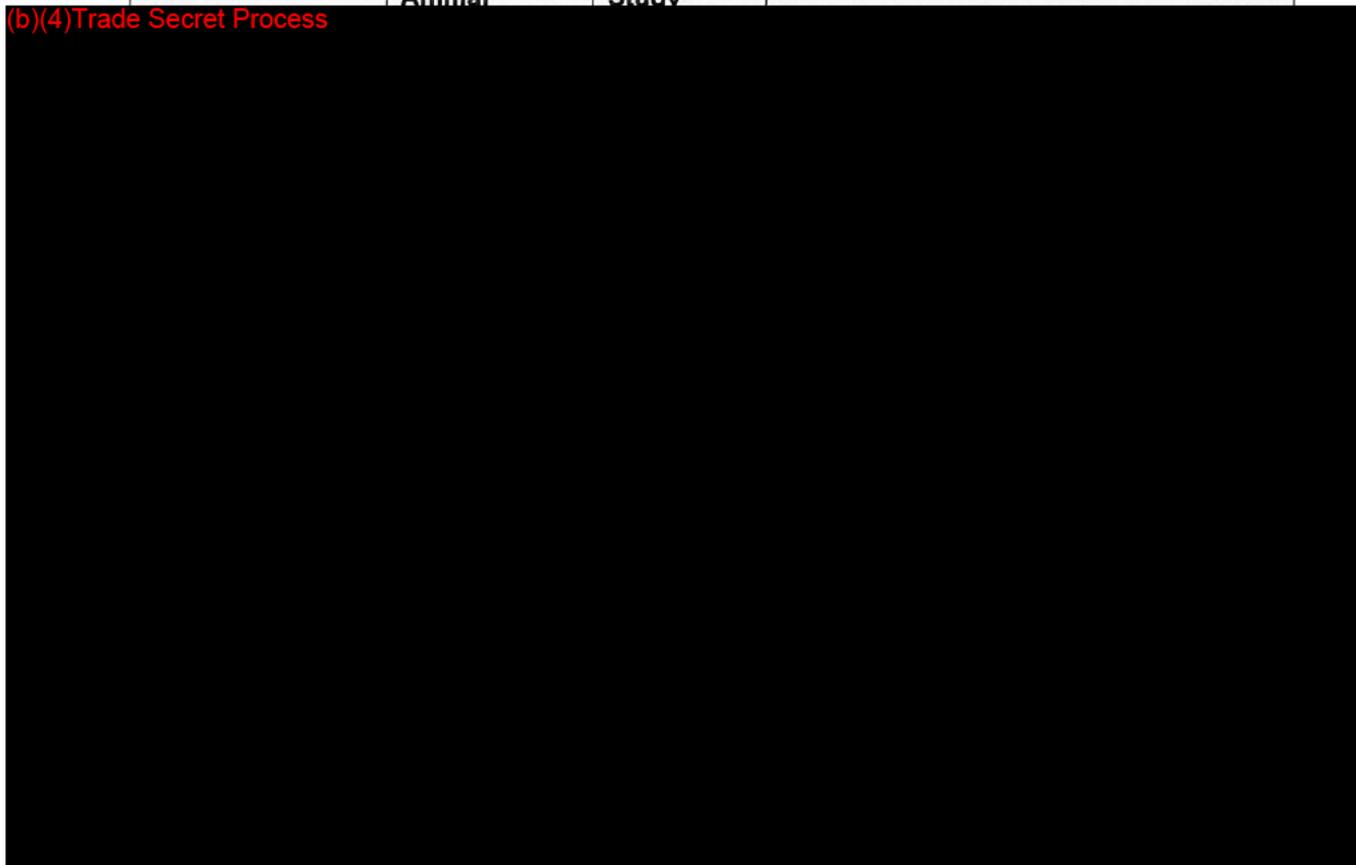
Performance Testing - Animal

(b)(4)Trade Secret Process



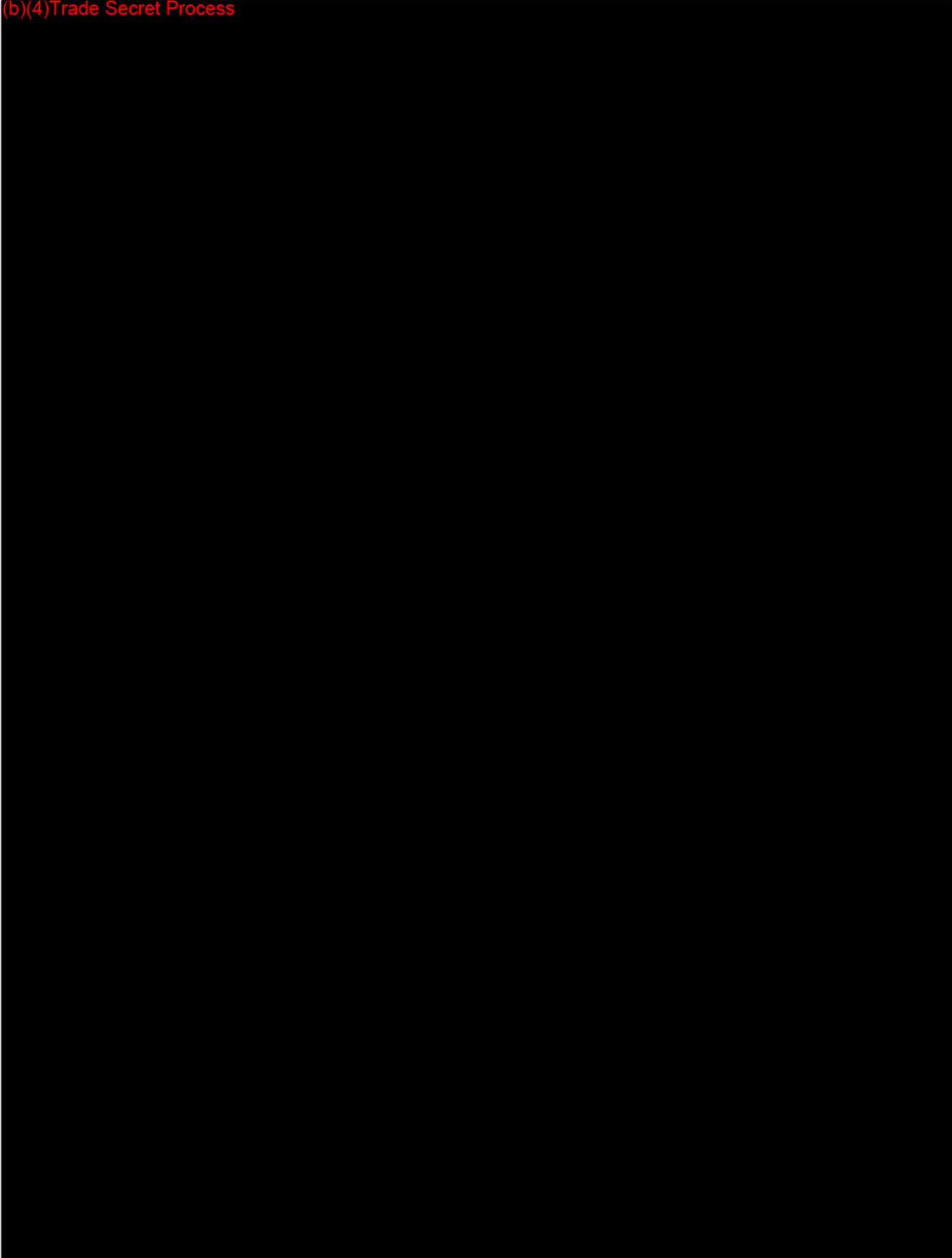
Reference	No. Animal	Duration of Study	Results and Conclusion
-----------	---------------	----------------------	------------------------

(b)(4)Trade Secret Process

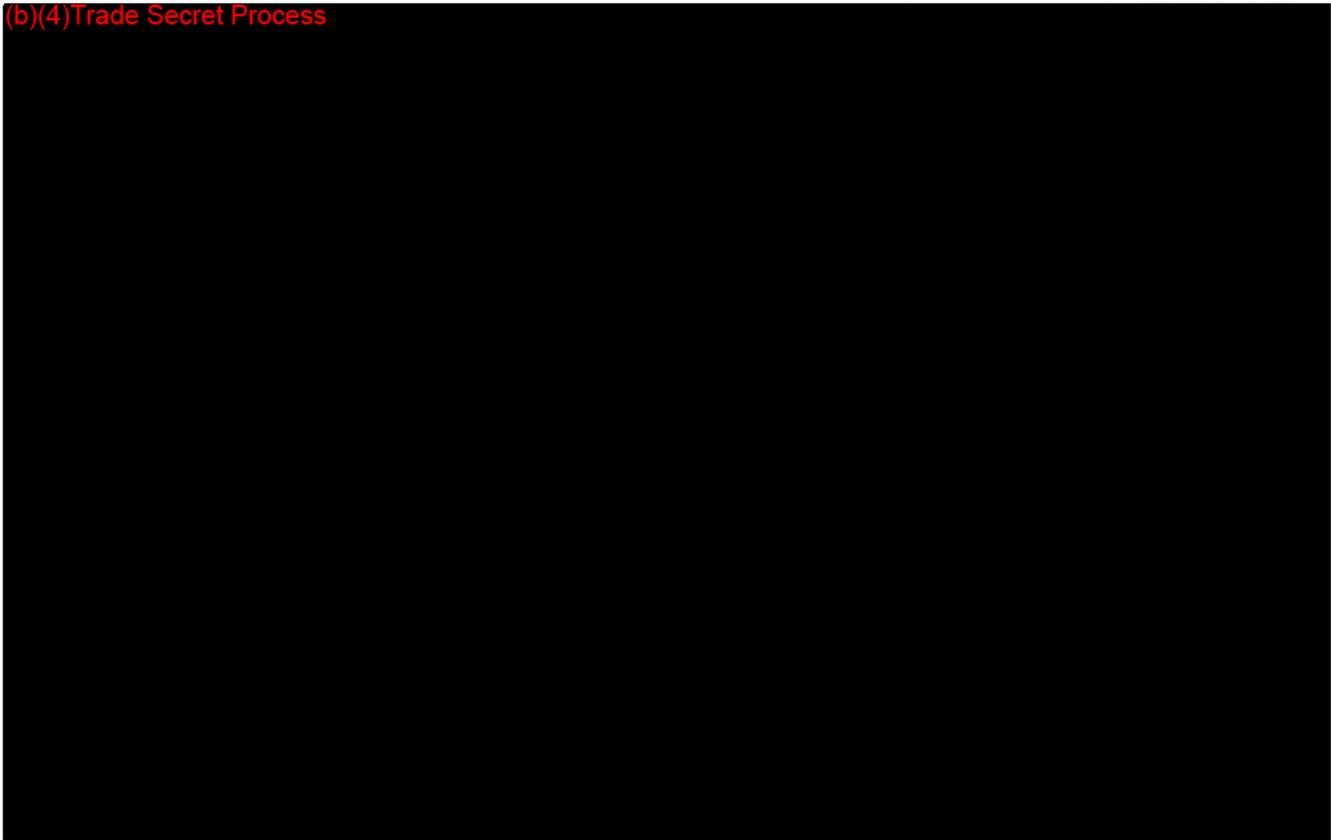


Reference	No. Animal	Duration of Study	Results and Conclusion
(b)(4) Trade Secret Process			

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



Sincerely,



Peggy Hansen, RAC
Vice President, Clinical, Regulatory, QA, and Marketing
Chief Regulatory Officer

Submitted in duplicate (hard copy and electronic)

ATTACHMENT A
REVISED OUTER BOX LABEL

REVISED OUTER BOX LABEL FOR FLEXIBLE COLLAGEN NERVE CUFF



+M440CNCF20250D



**\$\$31404301104231032DZ*

LOT

1104231032
Lot Number



2014-04
Expiration Date



See instructions
for use

STERILE R

Sterile by
Gamma Irradiation



30°C/86°F
Temperature
Limitation



Single
Use Only

CE 0086

R_x ONLY

REF CNCF2025

Size: 2 mm (inner diam) x 2.5 cm (length)

QTY 1

Distributed by:

stryker[®]
Mahwah, NJ 07430 USA

Manufacturer:

 Collagen Matrix, Inc.
15 Thornton Rd
Oakland, NJ 07436 USA

European Authorized Rep:

 MDSS Schiffgraben 41
D-30175 Hannover Germany

NF2025LS, Draft 0

ATTACHMENT B

**RED-LINED AND CLEAN COPY OF REVISED
510(k) SUMMARY**

510(k) SUMMARY

1. Applicant Information

Applicant Name: Collagen Matrix, Inc.
Address: 15 Thornton Road
Oakland, New Jersey 07436
Telephone: (201) 405-1477
Fax: (201) 405-1355
Contact Person: Peggy Hansen, RAC
VP, Clinical, Regulatory, QA, and Marketing
Date Prepared: March 6, 2014

2. Name of the Device

Device Common Name: Nerve Cuff
Device Trade Name: Flexible Collagen Nerve Cuff
Device Classification Name: Nerve cuff
882.5275
JXI
Class II

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): Collagen Nerve Cuff
K012814

Silastic® Nerve Cuff
Pre-amendment Device

4. Description of the Device

Flexible Collagen Nerve Cuff is a resorbable, flexible type I collagen tubular matrix that provides both an encasement for peripheral nerve injuries as well as protection of the neural environment. Flexible Collagen Nerve Cuff is designed to be an interface between the nerve and the surrounding tissue (e.g., to prevent ingrowth of scar tissue). When placed at the terminal end of a nerve, the Flexible Collagen Nerve Cuff is designed to prevent formation of neuroma. When hydrated, Flexible Collagen Nerve Cuff is a flexible collagen conduit where the crimped walls provide a kink-resistant property to the tube. It is supplied sterile, non-pyrogenic, in various sizes and for single use only.

5. Indications for Use / Intended Use

Flexible Collagen Nerve Cuff is used for the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.

6. Summary/Comparison of Technical Characteristics

Flexible Collagen Nerve Cuff is the identical product to the Company's currently marketed Neuroflex™ Collagen Nerve Cuff. The 510(k) premarket notification was submitted for expanded indications.

Parameter	Flexible Collagen Nerve Cuff (This submission)	Collagen Nerve Cuff K012814	Silastic® Nerve Cuff
Indications for Use	Intended for use in the management of peripheral nerve injuries in discontinuities where gap closure can be achieved by flexion of the extremity (e.g., to prevent ingrowth of scar tissue) or at the end of the nerve to prevent the formation of neuroma.	Intended for use in the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.	Intended to be used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).
Material	Type I collagen	Type I collagen	Silicone
Source	Bovine tendon	Bovine tendon	Synthetic
Form	Tubular matrix	Tubular matrix	Tubular matrix
Color	White to off-white	White to off-white	Opaque
Sizes	2 mm ID x 2.5 cm length 2.5 mm IDx 2.5 cm length 3 mm ID x 2.5 cm length 4 mm ID x 2.5 cm length 5 mm ID x 2.5 cm length 6 mm ID x 2.5 cm length	2 mm ID x 2.5 cm length 2.5 mm IDx 2.5 cm length 3 mm ID x 2.5 cm length 4 mm ID x 2.5 cm length 5 mm ID x 2.5 cm length 6 mm ID x 2.5 cm length	3.3 mm ID x 1.0 cm length 4.1 mm ID x 1.0 cm length 4.8 mm ID x 1.0 cm length 5.3 mm ID x 1.3 cm length 6.1 mm ID x 1.3 cm length 7.1 mm ID x 1.3 cm length 7.9 mm ID x 1.5 cm length 8.6 mm ID x 1.5 cm length 9.9 mm ID x 1.5 cm length 10.7 mm IDx 1.5 cm length 11.7 mm IDx 1.8 cm length 13.7 mm IDx 1.8 cm length
Mechanical Strength	Can be sutured	Can be sutured	Can be sutured
Resorbable	Yes	Yes	No
Crosslinked	Yes	Yes	No
Porosity/ Permeability	Semi-permeable. Permeable to nutrients and macromolecules	Semi-permeable Permeable to nutrients and macromolecules	Non-permeable
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Sterility	Sterile, SAL 10 ⁻⁶ Gamma irradiation	Sterile, SAL 10 ⁻⁶ Gamma irradiation	Sterile
Pyrogenicity	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml	Non-pyrogenic Endotoxin ≤ 0.5 EU/ml	Unknown
Single Use/Reuse	Single use only	Single use only	Single use only
Packaging	Double peel package	Double peel package	Sterile vials of distilled water

Nonclinical Tests Submitted

The substantial equivalence of the Flexible Collagen Nerve Cuff and its predicate device was demonstrated based on an evaluation of the expanded indications.

In vitro characterization studies included evaluation of physical properties such as suture strength, kink resistance, and an evaluation of physicochemical properties such as product permeability and hydrothermal transition temperature. The characterization test results of the subject device were equivalent to those of the predicate device, given that there has been no change to the device itself.

The Flexible Collagen Nerve Cuff material was evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The representative product passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices.

Test	Results	Conclusions
Cytotoxicity - Agarose Overlay	No evidence of causing any cell lysis or toxicity.	Non-cytotoxic
Sensitization - Guinea Pig Maximization	No evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig test.	Non-sensitizer
Intracutaneous Reactivity	Under the conditions of the study, there was no irritation or toxicity from the extract injected intracutaneously into rabbits.	Non-irritant, non-toxic
Acute Systemic Toxicity	No mortality or evidence of systemic toxicity	Non-toxic (acute systemic)
Genotoxicity - Bacterial Reverse Mutation	Non-mutagenic to <i>Salmonella typhimurium</i> and to <i>Escherichia coli</i> strain WP2uvra	Non-mutagenic
Mouse Lymphoma Assay	None of the test article treatments induced substantial increases in the number of revertant colonies.	Non-mutagenic
In Vivo Mouse Micronucleus Assay	None of the mice treated with the test article preparations exhibited overt signs of toxicity either immediately post-treatment or during the induction period. The levels of micronucleated cells were within normal negative ranges.	Non-mutagenic
Pyrogenicity - Rabbit Pyrogen	Non-pyrogenic	Non-pyrogenic

Test	Results	Conclusions
Muscle Implantation	The macroscopic reaction was not significant compared with the USP negative control implant material. Microscopically, the test article was classified as a nonirritant as compared to the USP negative control article.	Non-irritant
Subacute/ Subchronic/ Chronic Toxicity	Minimum tissue reaction up to 24 weeks of implantation and no adverse tissue reaction to the host.	Non toxic (subacute, subchronic, chronic)

Viral inactivation studies were performed to ensure the viral safety of the product.

Clinical Test Submitted

A clinical study was submitted that evaluated the use of the Flexible Collagen Nerve Cuff in the management of painful neuromas of the foot. A total of 50 patients underwent excision of painful single or multiple neuromas with the end of the resected nerve sutured into the Flexible Collagen Nerve Cuff subject device. Each patient preoperatively was asked to describe the amount of pain he or she was experiencing on a scale from 1 to 10, with 10 indicating the most severe pain. In the telephone interview conducted during this study, the same question was asked of each patient following revision. Patient ages ranged from 16 to 77 years, with a mean of 54 years. In all, 30 right and 20 left sides were operated, and 1 patient had bilateral involvement. Mean follow-up was 36 months (6-55 months). There were a total of 60 nerves that underwent conduit procedures in the foot. The results showed a 93% success rate of reducing pain for the treatment of neuroma in the foot.

Conclusions Drawn from Non-clinical and Clinical Studies

The results of the material evaluation, *in vitro* product characterization studies, biocompatibility studies, animal and clinical studies show that the Flexible Collagen Nerve Cuff is safe and substantially equivalent to the predicate device. The expanded indication for use does not affect the safety and performance of the device.

