APR 0 3 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
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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 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

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 G95-1and 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 *Salmonella typhimurium* and to *Escherichia coli* 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

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

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