DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 1 ,2017

Collagen Matrix, Inc.
Peggy Hansen
Senior Vice President
15 Thornton Road
Oakland, New Jersey 07436

Re: K170656
Trade/Device Name: Reinforced Flexible Collagen Nerve Cuff
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: March 2, 2017
Received: March 3, 2017

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

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -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 below.

510(k) Number *(if known)*
K170656

Device Name
Reinforced Flexible Collagen Nerve Cuff

Indications for Use *(Describe)*
Reinforced 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).

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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
SVP, Quality and Regulatory Affairs

Date Prepared: April 28, 2017

2. Name of the Device

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

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s): Flexible Collagen Nerve Cuff
K131541

4. Description of the Device

Reinforced Flexible Collagen Nerve Cuff is a resorbable, flexible type I collagen tubular matrix circumferentially supported with a resorbable synthetic polymer filament. The device provides both an encasement for peripheral nerve injuries as well as protection of the neural environment. The synthetic polymer filament provides enhanced support for biomechanical stability and kink-resistance of the collagen conduit. The Reinforced Flexible Collagen Nerve Cuff is an interface between the nerve and the surrounding tissue to prevent ingrowth of scar tissue. When implanted at a severed peripheral nerve gap, the Reinforced Flexible Collagen Nerve Cuff provides guidance for axonal growth across the gap. Upon hydration, the Reinforced Flexible Collagen Nerve Cuff is a soft, flexible collagen conduit with compression-resistant and kink-resistant properties. It is supplied sterile, non-pyrogenic, in various sizes and for single use only.

5. Indications for Use

Reinforced 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).

6. Summary/Comparison of Technical Characteristics

Parameter	Reinforced Flexible Collagen Nerve Cuff (This submission)	Flexible Collagen Nerve Cuff K131541
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).	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 prevent the formation of symptomatic or painful neuroma.
Material	Type I collagen with absorbable polymeric suture filament	Type I collagen
Source of collagen	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 Addition of a 3.0 cm length size for all diameters.	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
Mechanical Strength	Can be sutured	Can be sutured
pH	6 - 9	6 - 9
Resorbable	Yes	Yes
Crosslinked	Yes	Yes
Biocompatibility	Biocompatible	Biocompatible
Sterility	Sterile, SAL 10^{-6} ETO sterilization	Sterile, SAL 10^{-6} Gamma irradiation
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

Nonclinical Tests Submitted

The substantial equivalence of the Reinforced Flexible Collagen Nerve Cuff to its predicate device was demonstrated based on an evaluation of the product safety, product characteristics, and performance in an animal model.

In vitro characterization studies included evaluation of physical properties such as suture pullout strength, compression resistance, 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.

The Reinforced Flexible Collagen Nerve Cuff subject device was evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility. The subject device passed all applicable tests in accordance with ISO 10993-1 and FDA Guidance on Use of International Standard ISO 10993-1 for the biological evaluation of medical devices within a risk management process.

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

Test	Test Method/Model	Results
Physical Characterization	Suture pullout, compression resistance, kink resistance, permeability, hydrothermal transition temperature	Test results of the finished subject device are comparable to the predicate device.
Animal Performance	Rat sciatic nerve study	Test results of the finished subject device are comparable to the predicate device.
Cytotoxicity	Agarose Overlay, ISO 10993-5 MEM Elution Using L-929 Mouse Fibroblast Cells, ISO 10993-5	Non-cytotoxic; No evidence of causing any cell lysis or toxicity. The test article scored '0' at 24, 48, and 72 ± 4 hours and is considered non-cytotoxic under the conditions of the test.
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 up to 72 hours.
Subchronic (Systemic) Toxicity	Systemic Toxicity in Rabbits, ISO 10993-11	No evidence of systemic toxicity or adverse findings specifically attributed to the test article up to 13 weeks.
Genotoxicity	Bacterial Reverse Mutation Study, ISO 10993-3	Non-mutagenic to *Salmonella typhimurium* (strains TA97a, TA98, TA100, TA1535) and to *Escherichia coli* (strain WP2-uvra)
	Mouse Lymphoma Assay, ISO 10993-3	Based on the criteria and conditions of the study protocol, the test article is considered non-mutagenic (non-genotoxic and non-clastogenic)

Test	Test Method/Model	Results
Material-Mediated Pyrogenicity	Rabbit Pyrogen study-USP <151>	Non-pyrogenic. None of the rabbits administered with the test article extract had a temperature rise ≥0.5°C at the observation time points.
Implantation	Local Tissue Reaction in a Subcutaneous Implant in Rabbits, ISO 10993-6	The test article result was considered acceptable at 2 weeks and 13 weeks when compared to the control article.
Haemocompatibility	Hemolysis Assay – Extract Method, ASTM F756-13	The test article was considered non-hemolytic under the test conditions employed.
Chronic Toxicity Degradation	Local Tissue Reaction and Resorption in a Subcutaneous Implant in Rabbits, ISO 10993-6	The test article result was considered acceptable at 26 weeks when compared to the control article. Resorption of test article and incorporation into new host collagen was advanced at 26 weeks.

Animal Study

In the animal study conducted, 48 rats underwent excision of a segment of the sciatic nerve. In 16 of 48 rats, the nerve injuries were treated with the subject device, in another 16 rats the nerve injuries were treated with the predicate device, and in the remaining 16 rats, the nerve injuries were treated with an autograft control. There were no procedure related complications or premature deaths in the study.

Animals were sacrificed at 12 weeks and 24 weeks. The nerve repair segments were evaluated by gross observation, histological, and histomorphometrical methods. The study demonstrated that nerve regeneration was robust for both the subject and predicate devices.

Conclusions Drawn from Non-clinical Studies

Subject and predicate device performance data were compared to support the safety of the subject device and demonstrate that the Reinforced Flexible Collagen Nerve Cuff should perform as intended in the specified use conditions.