June 21, 2024

Mochida Pharmaceutical Co., Ltd.
% Kelliann Payne
Partner
Hogan Lovells U.S. LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K233322
Trade/Device Name: Mochida Nerve Cuff
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: May 24, 2024
Received: May 24, 2024

Dear Kelliann Payne:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2024.06.21 17:44:13 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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: 06/20/2023
See PRA Statement on last page

510(k) Number *(if known)*

K233322

Device Name

Mochida Nerve Cuff

Indications for Use *(Describe)*

Mochida Nerve Cuff is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity, or the management of peripheral nerve injuries in which there has been no substantial loss of nerve 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)

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)*

510(k) SUMMARY
Mochida's Nerve Cuff

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Mochida Pharmaceutical Co., Ltd.
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Contact: Akiko Koarai, Head of Medical Device Quality Management and Regulatory Affairs Department

Date Prepared: June 20, 2024

Name of Device

Trade name: Mochida Nerve Cuff
Common name: Cuff, Nerve
Classification name: Nerve cuff (21 CFR 882.5275)
Regulatory class: II
Product code: JXI

Predicate Devices

Collagen Matrix, Inc.'s Collagen Nerve Wrap (K060952) (Predicate device)
Collagen Matrix, Inc.'s Collagen Nerve Cuff (K012814) (Predicate device)

Device Description

The Mochida Nerve Cuff is made from a polyglycolic acid (PGA) sheet embedded into covalently cross-linked alginate gel, which is produced into a sponge form by freeze-drying and pressing into sheets.

The device is designed to repair peripheral nerve function by supporting the extension of the axon by providing a scaffold for growth of axons and Schwann cells following the degradation/absorption process after nerve injury. The device is to be implanted to cover the damaged, severed or excised section of the nerve axons.

When used, the device is cut according to the size of the nerve axon injury site, and fixed in place to cover the site.

Indications for Use

Mochida Nerve Cuff is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity, or the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

Comparison of Technological Characteristics with the Predicate Device

The subject device has similar technological characteristics as the predicate devices. Both are smooth, flexible products that are made of biodegradable materials, and are supplied in sterilized packages and for single use. Both devices aim to achieve the function of nerve repair through supporting nerve axon regeneration by providing a scaffold for growth of axons following the degradation/absorption process after nerve injury.

Both the subject and the predicate devices are made of biodegradable material. Specifically, the subject device consists of covalently cross-linked alginate gel, which is biodegradable, similar to the collagen material used in the predicate device.

Both the subject and the predicate devices are supplied in sheet/wrap forms. Both devices have the same fundamental science, which is to serve as scaffolds for Schwann and nerve cells to grow and to protect the regrowth site from the environment, such as ingrowth of scar tissue.

Both the subject and predicate devices remain in the body for a period of time until the injured nerves are repaired. The comparative animal studies showed similar host reaction and nerve regeneration between the subject device and Collagen Nerve Cuff predicate. Both the subject and predicate devices are provided sterile and are intended for single use. Sterilization validation testing demonstrated that the sterilization method used for the subject device is adequate to achieve sterility of the device. In addition, biocompatibility testing showed the biological safety of the device, further supporting the adequacy of the sterilization.

	Mochida Nerve Cuff (Subject device)	**Collagen Matrix, Inc.'s Collagen Nerve Wrap (K060952) (Predicate device)**	**Collagen Matrix, Inc.'s Collagen Nerve Cuff (K012814) (Predicate device)**
Regulation	21 CFR 882.5275	21 CFR 882.5275	21 CFR 882.5275
Product Code	JXI	JXI	JXI
Resorbable	Yes	Yes	Yes
Suturable	Yes	Yes	Yes
Material	Sodium Alginate Polyglycolic acid	Collagen	Type I Collagen
Indications For Use	Mochida Nerve Cuff is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity, or the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.	Collagen Nerve Wrap is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue and where gap closure can be achieved by flexion of the extremity.	Collagen Nerve Cuff is intended for use in repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

	Mochida Nerve Cuff (Subject device)	Collagen Matrix, Inc.'s Collagen Nerve Wrap (K060952) (Predicate device)	Collagen Matrix, Inc.'s Collagen Nerve Cuff (K012814) (Predicate device)
Physical structure	Sheet	Wraps (Pre-rolled membrane)	Tubular matrix
Size	5.5 cm × 5.5 cm (Long ×Wide) Can be cut to appropriate size	4 x 25 mm 4 x 50 mm 6 x 25 mm 6 x 50 mm 12 x 25 mm 12 x 50 mm Can be trimmed or shaped to appropriate size	Diameter: 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 10.0 mm; Lengths of 1, 2 and 3 cm.
Biocompatibility	Yes	Yes	Yes
Preparation for use	Use dry or minimally hydrated	Hydrated for 5 minutes in saline	Hydrated for 5 minutes in saline
Reusable	Single-use	Single-use	Single-use
Sterilization Method	eBeam	Gamma irradiation	Gamma irradiation
Packaging	Double Pouch	Double blister	not publicly available
Shelf life	4 months	3 years	3 years

Performance Data

The technical characteristics of the subject and predicate devices have been tested using comparative bench tests, which showed very similar results. In addition, performance testing, including biocompatibility testing and animal testing, demonstrates similar safety and performance of the subject device and its predicates. The following performance testing has been conducted:

Stability testing of the product and the packaging

Stability of the Mochida Nerve Cuff was demonstrated by the real-time and accelerated aging methodologies for the product and the packaging materials.

Transportation testing

The transportation testing was conducted to demonstrate the ability of the Mochida Nerve Cuff and its packaging to withstand the distribution environment. The testing was conducted according to ASTM D4169-22.

Pyrogenicity testing

Mochida Nerve Cuff is labeled as non-pyrogenic. Endotoxin testing was conducted to demonstrate that the product is non-pyrogenic.

Biocompatibility testing

Biocompatibility testing was conducted according to FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.""

Test	Test Summary	Conclusions
Chemical characterization	The chemical characterization was implemented based on ISO 10993-18. The extractable and leachable that could be released from the test article were identified and quantified.	The study did not identify any analytes that represent a significant toxicological risk.
Cytotoxicity	The device was evaluated for potential cytotoxic effects following ISO 10993-5 guidelines.	The cytotoxicity test results do not raise any safety concerns.
Sensitization	The device was evaluated for the potential to cause sensitization in guinea pigs based on ISO 10993-10. The test animals showed no evidence of inducting sensitization.	Non-sensitizing
Irritation	The device was evaluated for the potential to cause irritation following intracutaneous injection in rabbits based on ISO 10993-23. The extracts of the test article show no evidence of irritation.	Non-irritant
Acute systemic toxicity	The device was evaluated for acute systemic toxicity in mice based on ISO 10993-11. No change was observed in general conditions or in necropsy.	No acute systemic toxicity
Subacute toxicity	The device was evaluated for acute systemic toxicity in rats based on ISO 10993-6 and ISO 10993-11. No abnormality occurred in general conditions or surgical sites after implantation.	No subacute systemic toxicity
Pyrogenicity	The device was evaluated for the potential to induce a pyrogenic response following intravenous injection in rabbits based on ISO 10993-11. The total rise of temperature was within acceptable range.	Non-pyrogenic
Genotoxicity - Bacterial Reverse Mutation	The device was evaluated for the potential to induce reverse mutations in *bacteria* per ISO 10993-3. The result indicated that the extracts of the device were not genotoxic.	Non-genotoxic
Genotoxicity - Chromosomal Abnormality	The device was evaluated for the potential of clastogenicity per ISO 10993-3. It showed that this device is clastogenicity negative in cultured mammalian cells.	Non-genotoxic

Test	Test Summary	Conclusions
Hemolysis testing	The device was evaluated for hemolytic potential when in contact with blood based on ISO 10993-4 and ASTM F756 standard. Under the conditions of this study, data obtained were considered not analyzable.	No conclusion was drawn for hemolytic potential of the treated test article extract.
Subchronic toxicity, Chronic toxicity, and Carcinogenicity	These endpoints were addressed with a chemical characterization/toxicological risk assessment approach.	Justified by chemical characterization/toxicological risk assessment

Bench testing

Comparative bench testing of Mochida Nerve Cuff and the predicate devices, including tensile strength, suture retention strength, pH, stiffness, degradation, swelling rate, and porosity testing, was conducted.

Test	Test Method Summary	Results
Tensile strength	The device is cut into a piece, and then pull both ends of the test piece and measure the strength when it breaks.	Pass
Suture retention strength	After passing a suture with a needle though the wetted specimen, fix the suture to blocks. Pull the specimen, and measure the strength at which the device breaks.	Pass
pH	Measure the pH of the sample extract of the device.	N/A (For reference)
Stiffness	Wrap sample around the smooth shaft and record any observation of cracking or breaking.	Pass
Degradation	Immerse the devise in a solution and measure the weight of the devise after picking up from the solution after a period of time.	N/A (For reference)
Swelling rate	Measure the absorbed amount of water per device weight.	N/A (For reference)
Porosity	Porosimetry	N/A (For reference)

Animal study

In addition to the bench testing, the subject device has also been tested in two animal studies using the rat sciatic nerve model. The first study evaluated the nerve repair process, article degradation and local tissue response to Mochida Nerve Cuff when applied to a sciatic nerve transection (nerve gap) in the rat for 1, 8, and 26 weeks, as compared to the Collagen Nerve Cuff predicate. The second study evaluated the article degradation and local tissue response to Mochida Nerve Cuff when applied to a sciatic nerve without transection (no substantial loss of nerve tissue) in the rat for 1, 8, and 13 weeks, as compared to the Collagen Nerve Wrap predicate. In addition to the test article and control article (predicate device), the studies also

included a sham arm to evaluate the response that could be elicited from the surgical procedures.

For all evaluated endpoints in both studies, including neurological findings and histology findings, the results demonstrated that the Mochida Nerve Cuff has the similar safety profile and performance as the predicate devices. Therefore, the results of the in vivo animal study support the substantial equivalence.

Conclusions

The Mochida Nerve Cuff and its predicate devices have the same intended use and similar indications, technological characteristics and principles of operation. The minor technological differences do not present any new issues of safety or effectiveness. Performance testing demonstrated that the subject device performs similarly as the predicate devices. Thus, the Mochida Nerve Cuff is substantially equivalent to the predicate devices.