January 29, 2024

CelestRay Biotech Company, LLC
Shanshan Xu
CTO and Partner
P.O. Box 341754
Bethesda, Maryland 20827-1754

Re: K230794
Trade/Device Name: Rebuilder Nerve Guidance Conduit
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: December 23, 2023
Received: December 29, 2023

Dear Shanshan Xu:

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: 2024.01.29 13:55:20 -05'00'

Adam Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
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and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230794

Device Name
Rebuilder Nerve Guidance Conduit

Indications for Use *(Describe)*
Rebuilder Nerve Guidance Conduit is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

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
K230794

Applicant information

Applicant Name:	CelestRay Biotech company, LLC
Applicant Address:	PO BOX 341754, BETHESDA, MD 20827-1754
Phone:	202-808-5668
Fax:	--
Contact Person:	Shanshan Xu CTO and Partner
Date Prepared:	January 25, 2024

Name of Device

Device Common Name:	Nerve Guide
Device Trade Name:	Rebuilder Nerve Guidance Conduit
Device Classification Name:	Nerve Cuff 882.5275 Class II JXI

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Primary Predicate Device	Neurolac Nerve guide, K112267 Polyganics BV.
Additional Predicate Device	Neurolac Nerve guide, K050573 Polyganics BV.
Reference Device	NeuroGen Nerve Guide, K011168 Integra LifeSciences Corporation

Description of the device

The Rebuilder Nerve Guidance Conduit is designed to be a permeable and bioresorbable poly(lactide-co-caprolactone) based tube. It is designed to serve as an interface between the nerve and the surrounding tissue, providing a protective environment for peripheral nerve repair after injury. The Rebuilder Nerve Guidance Conduit offers guidance and protection for axonal growth across a nerve gap.

The Rebuilder Nerve Guidance Conduit is provided sterile, non-pyrogenic, for single use only, in various sizes (with product inner diameter ranging from 1.5mm to 10 mm). The Rebuilder Nerve Guidance Conduit is provided in double peel package.

Indications for Use

Rebuilder Nerve Guidance Conduit is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

Summary/Comparison of Technical Characteristics

Haracteristic	Subject Device	Predicate Device	Predicate Device	Reference Device
Device Name	Rebuilder Nerve Guidance Conduit	Neurolac Nerve Guide (K112267)	Neurolac Nerve Guide (K050573)	Neurogen Nerve Guide (K011168)
Indications for use	Rebuilder Nerve Guidance Conduit is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.	The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.	The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.	The Collagen Nerve Cuff is intended for use in repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.
Principle of Operation	To serve as an interface between the nerve and the surrounding tissue, providing a protective environment for	To provide a protective environment for peripheral nerve regeneration after injury and to create a conduit to	To provide a protective environment for peripheral nerve regeneration after injury and to create a conduit to	To provide a protective environment for peripheral nerve repair after injury, to be an interface between the nerve and

	peripheral nerve repair after injury, and to offer guidance and protection for axonal growth across a nerve gap.	guide axonal growth across a nerve gap.	guide axonal growth across a nerve gap.	surrounding tissue and to create a conduit for axonal growth across a nerve gap.
Design	A permeable tube with inner diameter ranging from 1.5mm to 10 mm, and length of 3 cm	A flexible and transparent tube with internal diameter of 1.5-3 mm, and length of 3 cm.	A flexible and transparent tube with internal diameter of 4-10 mm, and length of 3 cm.	A porous tube with inner diameter of 2 - 7mm, and length of 2 cm to 4 cm.
Material	poly(lactide-co-caprolactone), Poly (lactic-co-glycolic acid) and Polylactic acid-b-Polyethylene glycol	poly(DL-lactide-co-ε-caprolactone)	poly(DL-lactide-co-ε-caprolactone)	Collagen
Resorbable Material	Yes	Yes	Yes	Yes
Sterilization	Ethylene Oxide to SAL of 10^{-6}	Ethylene Oxide to SAL of 10^{-6}	Ethylene Oxide to SAL of 10^{-6}	Ethylene Oxide to SAL of 10^{-6}
Single Use /Reuse	Single use only	Single use only	Single use only	Single use only
Packaging	Tyvek paper-plastic bag, and an aluminum foil bag	Single use, polycarbonate tray, single Tyvek pouch, cardboard box	Single use, polycarbonate tray, single Tyvek pouch, cardboard box	Double blister packages
Product Code	JXI	JXI	JXI	JXI
CFR Section	882.5275	882.5275	882.5275	882.5275

Performance Testing

The Rebuilder Nerve Guidance Conduit and its predicates have been characterized for performance with mechanical strength to demonstrate substantial equivalence. Non-Clinical Tests were conducted and performed on the subject device and predicate device,

including suture retention strength, compression properties, as well as chemical analysis and degradation properties. The test demonstrates the proposed device is substantial equivalent to the legally marketed predicate device.

The biocompatibility testing of the product was performed according to ISO 10993-1:2018 Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process under the category of implant device, tissue/bone contact, permanent duration (>30 days), including Cytotoxicity, Sensitization, Intracutaneous reactivity, Systemic toxicity(acute), Genotoxicity, Implantation (with histology of the surrounding tissue), Hemolysis, Pyrogenicity, Subchronic systemic toxicity and Chronic systemic toxicity. All test results showed that the Rebuilder Nerve Guidance Conduit is biocompatible. The tests helped demonstrate that the device is substantially equivalent to its predicate.

In *vivo* animal testing was performed using a rat nerve sciatic nerve transection model. The transected nerves were implanted with either the Rebuilder Nerve Guidance Conduit (test article) to the Neurolac Nerve Guide (comparator control), and rats were evaluated at the 1-, 3- and 6-month evaluation time points for healing responses. Outcome measures included macroscopic assessment of the nerve implant sites for tissue adhesions, clinical pathology (hematology and serum chemistry), in-life assessments of animal wellness, functional recovery as assessed using a Sciatic Function Index of walking tracks, and semi-quantitative histological assessments for inflammation, nerve fiber density, axonal myelination. The results demonstrate the substantial equivalence of the Rebuilder Nerve Guidance Conduit to the Neurolac Nerve Guide in facilitating nerve repair and functional recovery.

Conclusion of Non-clinical test

The results of the mechanical performance, biocompatibility and animal testing demonstrated that the Rebuilder Nerve Guidance Conduit is substantially equivalent to Neurolac Nerve Guide, K112267.