July 6, 2023

CelestRay Biotech Company, LLC
Dr. Charles C. Han
PO Box 341754
Bethesda, Maryland 20827-1754

Re: K222220
Trade/Device Name: SpinMedix Absorbable Fibrous Membrane
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWW, FTL
Dated: May 24, 2023
Received: May 24, 2023

Dear Charles Han:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Jesse Muir -S

Jesse Muir, PhD
Assistant Director
DHT6C: Division of Retorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K222220

Device Name
SpinMedix Absorbable Fibrous Membrane

Indications for Use *(Describe)*
The SpinMedix Fibrous Membrane is indicated for management and protection of tendon injuries in which there has been no substantial loss of tendon 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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Biotech company, LLC

5. 510(k) Summary

Applicant information

Applicant Name:	CelestRay Biotech company, LLC
Applicant Address:	PO BOX 341754, BETHESDA, MD 20827- 1754
Phone:	202-808-5668
Fax:	--
Contact Person:	Charles C. Han General Manager and Partner
Date Prepared:	Oct 19, 2022

Name of Device

Device Common Name:	Soft Tissue Reinforcement Mesh
Device Trade Name:	SpinMedix® Absorbable Fibrous Membrane
Device Classification Name:	Mesh, Surgical 878.3300 Class II OWW, FTL

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s)	Surgi-Wrap MAST Tendon Sheet, K063648 MAST Biosurgery Inc. San Diego, CA TAPESTRY® Biointegrative Implant, K201572 Embody, Inc. Norfolk, VA

Description of the device

SpinMedix Absorbable Fibrous Membrane provides a non-constricting protective layer between the injured tissue and surrounding tissues and may be secured in place using standard fixation techniques. It is designed for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. SpinMedix is composed of poly (D, L-Lactide-co- Glycolide) and poly (D, L-Lactide-b-Ethylene Glycol), and is provided in a variety of sizes, ranging from 25mm * 25mm to 200mm * 300mm. It is a single use, sterilized, porous, polymeric membrane in double peel packages.

Indication for Use

The SpinMedix Fibrous Membrane is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Summary/ Comparison of Technical Characteristics

Haracteristic	Subject Device	Predicate Device	Reference Device
Device Name	SpinMedix® Absorbable Fibrous Membrane	MAST Biosurgery Surgi-Wrap MAST Tendon Sheet (K063648)	TAPESTRY Biointegrative Implant (K201572)
Indication for Use	The SpinMedix Fibrous Membrane is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.	The Surgi-Wrap MAST Tendon Sheet is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The resorbable Protective Film minimizes tissue attachment to the device in case of direct contact with the tissues. The Surgi-Wrap MAST Tendon Sheet is also indicated for reinforcement of soft tissues repaired by suture or suture anchors, during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Surgi-Wrap MAST Tendon Sheet is	TAPESTRY® is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

		not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear and sutures or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair. The Surgi-Wrap MAST Tendon Sheet reinforces soft tissue and provides a remodelable scaffold that is replaced by the patients' own soft tissue.	
Design	Sheets ranging in size from 25mm x 25mm to 200mm x 300mm with thickness of 0.08mm – 0. 16mm	Sheets ranging in size from 25mm x 25mm to 500mm x 500mm with thickness of 0.02mm-1.0mm	Multiple sizes from 2.0cm x 2.5cm to 7.0cm x 5.0cm
Material	Poly(D,L-lactide-co-glycolide) and poly (D, L-lactide-b-ethylene glycol)	Poly(L-lactide-co-D,L-lactide)	Highly aligned composite implant (70% PDLLA, 30% type I bovine Collagen) non-crosslinked
Appearance	Fibrous membrane with porous structure	Dense film without micropattern	White to off white with blue orientation lines on unaligned side
Resorbable Material	Yes	Yes	Yes
Sterilization	Ethylene Oxide to SAL of 10^{-6}	eBeam Irradiation to SAL of 10^{-6}	Electron Beam to SAL of 10^{-6}
Pyrogenicity	Non-pyrogenic (< 20EU/device)	Non-pyrogenic	Non- pyrogenic (< 1 EU/device)
Single Use /Reuse	Single use only	Single use only	Single use only

Packaging	Dry packaged in a high-barrier, double foil pouch with secondary sterile barrier	a Tyvek® pouch and a foil pouch with secondary sterile barrier	Dry packaged in a high-barrier, double foil pouch with secondary sterile barrier
Storage Conditions	Store at temperature -4 to 86˚F (-20 to 30˚C)	Store at controlled room temperature 59–86˚F (15–30˚C)	Room temperature / ambient
Product Code	OWW, FTL	FTL	OWY
CFR Section	878.3300	878.3300	878.3300

Equivalence to Marketed Products

SpinMedix® Absorbable Fibrous Membrane and its predicates have been characterized for performance with mechanical strength to demonstrate substantial equivalence. Testing was conducted in accordance with to FDA's *Guidance for the Preparation of a Premarket Notification Applicationfor a Surgical Mesh (March 1999)*.

Biocompatibility Testing for SpinMedix® Absorbable Fibrous Membrane including, cytotoxicity, sensitization, intracutaneous irritation, systemic toxicity, pyrogenicity, and genotoxicity satisfied the requirements outlined in ISO 10993- 1 *(2009 & 2018) Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk managementprocess,* and helped demonstrate that the device is substantially equivalent to its predicate and is biocompatible in accordance to ISO 10993- 1.

The *in vivo* animal study evaluated local tissue response, systemic toxicity, and the device resorption profile in a clinically relevant tendon model. SpinMedix® Absorbable Fibrous Membrane was found to be completely resorbed between the 16 to 20-week time points with a complete quiescence of the associated inflammatory response. The device was shown to yield favorable results in the calcaneal tendon incision model and inguinal hernia model and supports a determination of substantial equivalence.

Conclusion of Non-clinical test

The results of the mechanical performance, biocompatibility and animal efficacy testing demonstrated that SpinMedix® Absorbable Fibrous Membrane is substantially equivalent to its predicate.