Elutia Inc.
Erica Elchin
Vice President, Quality & Regulatory Affairs
1100 Old Ellis Road
Suite 1200
Roswell, Georgia 30076

Re: K233991
Trade/Device Name: CanGaroo RM Antibacterial Envelope
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: May 17, 2024
Received: May 17, 2024

Dear Erica Elchin:

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,

Jessica L. Batista -S

Digitally signed by Jessica L. Batista -S
Date: 2024.06.14 16:31:50 -04'00'

for

Sara Royce
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233991

Device Name
CanGaroo RM Antibacterial Envelope

Indications for Use *(Describe)*
The CanGaroo® RM Antibacterial Envelope is intended to securely hold a cardiac implantable electronic device or an implantable neurostimulator to create a stable environment when implanted in the body. The cardiac implantable electronic devices that may be used with the CanGaroo RM Antibacterial Envelope include pacemaker pulse generators, defibrillators, and other cardiac implantable electronic devices. The implantable neurostimulator devices that may be used with the CanGaroo RM Antibacterial Envelope include vagus nerve stimulators, spinal cord neuromodulators, deep brain stimulators, sacral nerve stimulators, and other neurostimulator devices.

The CanGaroo RM Antibacterial Envelope contains the antibiotics rifampin and minocycline, which have been shown in preclinical testing to reduce bacterial colonization on the envelope. Overall clinical benefit has not yet been evaluated.

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.

510(k) Summary

This 510(K) Summary is provided per the requirements of Section 807.92(c)

Company Information

Company Name:	Elutia Inc. 1100 Old Ellis Road, Suite 1200, Roswell, GA 30076
Contact Name:	Erica Elchin
Contact Email:	eelchin@elutia.com
Contact Title:	VP, Quality & Regulatory Affairs
Phone:	877-651-2628

Date Prepared: June 14, 2024

Device Information

Trade Name:	CanGaroo® RM Antibacterial Envelope
Common Name:	Surgical Mesh Envelope
Classification Name:	Surgical Mesh
Regulation Number:	21 CFR 878.3300
Product Code:	FTM
Device Class:	Class II

Predicate Device

The CanGaroo® RM Antibacterial Envelope is substantially equivalent to the following device:

- TYRX™ Absorbable Antibacterial Envelope, K192389

CanGaroo® (K201313), LUOFUCON® PHMB Alginate Dressing (K201016), and XenMatrix™ AB Surgical Graft (K162193) are reference devices.

Device Description

The CanGaroo® RM Antibacterial Envelope consists of decellularized, non-crosslinked, lyophilized extracellular matrix (ECM) and resorbable ring-shaped poly(lactide-co-glycolide) (PLGA) discs containing the antibiotics rifampin and minocycline. The ECM material is derived from porcine small intestinal submucosa (SIS). The envelope is constructed with four multilaminate sheets, perforated to allow for exudate. The drug-eluting polymer discs are secured between the multilaminate sheets on each side of the envelope.

The CanGaroo RM Antibacterial Envelope is intended to securely hold an implantable electronic device (IED) to create a stable environment when implanted in the body, while reducing bacterial colonization with rifampin and minocycline eluted from resorbable polymer discs in the envelope. The CanGaroo RM Antibacterial Envelope is based on the existing CanGaroo Envelope (K201313), with the addition of drug-eluting disc components with the antibiotics rifampin and minocycline.

The CanGaroo RM Antibacterial Envelope is provided sterile in two sizes and is intended for single use in a single patient only.

CanGaroo RM Antibacterial Envelope	Envelope Size W x L	# of discs	Rifampin	Minocycline
Medium	6.9 cm x 6.5 cm	2	10.5 mg	9.3 mg
Large	6.9 cm x 8.0 cm	2	10.5 mg	9.3 mg

Indications for Use

The CanGaroo RM Antibacterial Envelope is intended to securely hold a cardiac implantable electronic device or an implantable neurostimulator to create a stable environment when implanted in the body. The cardiac implantable electronic devices that may be used with the CanGaroo RM Antibacterial Envelope include pacemaker pulse generators, defibrillators, and other cardiac implantable electronic devices. The implantable neurostimulator devices that may be used with the CanGaroo RM Antibacterial Envelope include vagus nerve stimulators, spinal cord neuromodulators, deep brain stimulators, sacral nerve stimulators, and other neurostimulator devices.

The CanGaroo RM Antibacterial Envelope contains the antibiotics rifampin and minocycline, which have been shown in preclinical testing to reduce bacterial colonization on the envelope. Overall clinical benefit has not yet been evaluated.

Summary of Technological Characteristics

The CanGaroo RM Antibacterial Envelope is designed to hold IEDs securely to create a stable environment when implanted in the body. The intended use of the CanGaroo RM Antibacterial Envelope is identical to the predicate device (K192389) and its technical characteristics are substantially equivalent.

The CanGaroo RM Antibacterial Envelope is based on the CanGaroo Envelope (K201313), with the addition of rifampin and minocycline drug-eluting discs. The envelope is made of the same material, porcine SIS, as the predicate CanGaroo Envelope. CanGaroo RM is a resorbable device, as is the predicate device.

The drug eluting discs contain the same antibacterial drugs, rifampin and minocycline, as the predicate device K192389. Antibiotic concentrations for CanGaroo RM span the range of the predicate device K192389 and the reference device K162193.

The device and the predicate are all terminally sterilized (e-beam or gamma irradiation).

The performance of CanGaroo RM and the predicate device all have been assessed through bench, *in vitro*, and *in vivo* testing. The results demonstrate that CanGaroo RM does not raise any new questions of safety and effectiveness.

Performance Data

The following performance data is provided in support of the substantial equivalence determination.

Performance Standards:

No performance standards have been established for this device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Biocompatibility Testing:

Biocompatibility testing in accordance with the current ISO 10993 series and FDA guidance was conducted on the subject device and the results indicate that the device is biocompatible per these standards. The testing included cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, and implantation studies.

Bench Testing:

Bench testing was completed for the CanGaroo RM Antibacterial Envelope. The subject device passed all test requirements. The following tests were conducted for the subject device:

- Physical Characteristics
  - Appearance
  - Dimensional
- Functional Characteristics
  - Seam Strength
- Antibacterial Effectiveness
  - Antibacterial Activity, *in vitro* (Modified AATCC 100)
    Utilizing AATCC methodology, CanGaroo RM demonstrated bacterial reduction against a panel of 4 gram positive and 3 gram-negative organisms.
- Drug Elution
  - Drug assay and drug elution/release testing.

Animal Testing:

- Pharmacokinetics, *in vivo*
- Bacterial Challenge model, *in vivo*
  A bacterial challenge model in rabbits showed clearance at day 7 following implantation for a panel of 3 gram positive and 3 gram negative organisms.

Conclusion

Performance data utilizing *in vitro* and *in vivo* testing demonstrates substantial equivalence to the predicate device (K192389). The CanGaroo RM device is as safe and as effective, with equivalent performance, to the legally marketed predicate device.