October 21, 2019

Aziyo Biologics, Inc.
Wendy Perreault
Regulatory Affairs Consultant
1100 Old Ellis Road, Suite 1200
Roswell, Georgia 30076

Re: K192616
Trade/Device Name: CanGaroo Envelope
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: September 19, 2019
Received: September 23, 2019

Dear Wendy Perreault:

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,

Timothy Marjenin
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192616

Device Name

CanGaroo Envelope

Indications for Use *(Describe)*

The CanGaroo 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 Envelope include pacemaker pulse generators, defibrillators, or other cardiac implantable electronic devices. The implantable neurostimulator devices that may be used with the CanGaroo Envelope include vagus nerve stimulators, spinal cord neuromodulators, deep brain stimulators and sacral nerve stimulators.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: K192616

Company Information

Company Name:	Aziyo Biologics, Inc.
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Date Prepared:	September 19, 2019

Product Information

Trade Name:	CanGaroo® Envelope
Common Name:	Surgical Mesh Envelope
Classification Name:	Surgical Mesh, 21 CFR 878.3300, Product Code FTM, Class II

Predicate Devices

The CanGaroo Envelope is substantially equivalent to the CanGaroo Envelope referenced in the Substantially Equivalent letter issued by FDA for 510(k) application K182255.

This Special 510(k) application describes a change in the labeled shelf life for the device based on results of shelf life testing of real-time aged product; there have been no modifications to the indications for use of the CanGaroo device and no changes to labeling are proposed (other than the expiration date that is populated on the product labels), and the change does not have the potential to alter the fundamental scientific technology of the device. The operating principle(s) and mechanism of action of the device are not changing.

Device Description

The CanGaroo 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 Envelope include pacemaker pulse generators, defibrillators, or other cardiac implantable electronic devices. The implantable neurostimulator devices that may be used with the CanGaroo Envelope include vagus nerve stimulators, spinal cord neuromodulators, deep brain stimulators and sacral nerve stimulators.

The CanGaroo Envelope is constructed from two to four perforated, multilaminate sheets (4-ply) of decellularized, non-crosslinked, lyophilized ECM (extracellular matrix) derived from porcine small

intestinal submucosa. The 3 mm perforations are spaced evenly at 10 mm apart to allow exit of any exudate. The ECM is assembled into pouch form using violet 5-0 polydioxanone suture (PDS).
The device design is identical to the device cleared under K182255.

Indications for Use

The CanGaroo 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 Envelope include pacemaker pulse generators, defibrillators, or other cardiac implantable electronic devices. The implantable neurostimulator devices that may be used with the CanGaroo Envelope include vagus nerve stimulators, spinal cord neuromodulators, deep brain stimulators and sacral nerve stimulators.

Substantial Equivalence

The intended use of the CanGaroo Envelope to securely hold a CIED or neurostimulator is identical to the intended use of the CanGaroo Envelope cleared under K182255. The devices are of identical design and are manufactured from the same materials.

Non-clinical Testing

Testing of real-time aged CanGaroo Envelopes was completed to supplement the accelerated aging results for the device, and included seam strength testing of the aged devices to ensure the requirements for seam strength were met at 30 months.

Conclusion

The CanGaroo Envelope labeled with a shelf life of 30 months is substantially equivalent to the predicate CanGaroo Envelope.