November 15, 2018

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

Re: K182255
Trade/Device Name: CanGaroo® Envelope
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: August 17, 2018
Received: August 20, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 A. Marjenin -S

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*

K182255

Device Name

CanGaroo(R) Envelope

Indications for Use *(Describe)*

The CanGaroo(R) 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) Summary: K182255**

Company Information


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|---|---|
| Company Name: | Aziyo Biologics, Inc. |
| Contact Name: | Wendy Perreault |
| Contact Title: | Regulatory Consultant |
| Address: | 1100 Old Ellis Rd., Suite 1200<br>Roswell, GA 30076 |
| Phone (office): | 678-566-2628 |
| Phone (mobile): | 404-542-5854 |
| Fax: | 678-736-5082 |


Date Prepared: August 17, 2018

Product Information

| | |
|---|---|
| Trade Name: | CanGaroo® Envelope |
| Common Name: | Surgical Mesh Envelope |
| Classification Name: | Surgical Mesh, 21 CFR 878.3300<br>Product Code FTM, Class II |
| Classification Panel: | Cardiovascular and/or Neurological and Physical Medicine Devices |

Predicate Devices

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

- CanGaroo® Envelope (K173242)

Device Description

The CanGaroo Envelope is a sterile device intended to securely hold a cardiac implantable electronic device or an implantable neurostimulator device to create a stable environment when implanted in the body. It is for single use in a single patient. The cardiac 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 perforated, multi-laminate sheets (4- ply) of decellularized, non-crosslinked, lyophilized extracellular matrix (ECM) derived from porcine small intestinal submucosa. The perforations are spaced evenly to allow exit of any exudate. The ECM is assembled into pouch form using violet 5-0 polydioxanone (PDS) suture.

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 cardiac implantable electronic device or an implantable neurostimulator is identical to the CanGaroo Envelope cleared in K173242. All devices are constructed as Envelopes. The subject CanGaroo Envelope is of identical design and manufactured from the same materials (SIS-ECM and polydioxanone suture) as the CanGaroo Envelope cleared in K173242.

Non-clinical Testing

The CanGaroo Envelope is intended to securely hold a cardiac implantable electronic device or an implantable neurostimulator device. The performance testing that supports the CanGaroo Envelope includes seam strength testing. The testing demonstrates that the design of the CanGaroo Envelope provides adequate biomechanical properties for use in the intended application.

Conclusion

The CanGaroo® Envelope is substantially equivalent to the predicate CanGaroo® Envelope (K173242).