October 25, 2017

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

Re: K173242
Trade/Device Name: CanGaroo Envelope
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: October 5, 2017
Received: October 6, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K173242

Device Name
CanGaroo(R) Envelope

Indications for Use *(Describe)*
The CanGaroo(R) Envelope is intended to securely hold a cardiac implantable electronic device to create a stable environment when implanted in the body. The devices that may be used with the CanGaroo Envelope include pacemaker pulse generators, defibrillators, or other cardiac implantable electronic devices.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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: K173242

Company Information

Company Name:	Aziyo Biologics, Inc.
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Date Prepared:	October 5, 2017

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 CorMatrix PROTECT ECM Envelope referenced in the Substantially Equivalent letter issued by FDA for 510(k) application K140306.

The device cleared under K140306 is marketed under the name CanGaroo® ECM® Envelope or CanGaroo® Envelope. This Special 510(k) application describes an alternate supplier of the suture used to manufacture the device; there have been no modifications to the indications for use of the CanGaroo device and no changes to labeling are proposed, 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 to create a stable environment when implanted in the body. The devices that may be used with the CanGaroo Envelope include pacemaker pulse generators, defibrillators, or other cardiac implantable electronic devices.

The CanGaroo Envelope is constructed from two 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 K140306.

Substantial Equivalence

The intended use of the CanGaroo Envelope to securely hold a CIED is identical to the intended use of the CorMatrix PROTECT ECM Envelope. The devices are of identical design and are manufactured from the same materials.

Non-clinical Testing

To ensure that the equivalent suture from a different supplier could be used to manufacture a product that continued to meet the design input requirements, seam strength testing of devices manufactured with the alternate suture was repeated; the CanGaroo Envelope manufactured with the alternate suture supplied by the new supplier met the design input requirements for seam strength.

Conclusion

The CanGaroo Envelope manufactured with an alternate, equivalent suture from a new supplier is substantially equivalent to the predicate device, the CorMatrix PROTECT ECM Envelope.