DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 28, 2017

Admedus Regen Pty Ltd
% Mary Donlin
Vice President Regulatory Affairs and Compliance
860 Blue Gentian Road, Ste 295
Eagan, Minnesota 55121

Re: K170951
Trade/Device Name: CardioCel 3D
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch Or Pledget Made Of Polypropylene, Polyethylene Terephthalate, Or Polytetrafluoroethylene
Regulatory Class: Class II
Product Code: PSQ
Dated: March 30, 2017
Received: March 31, 2017

Dear Ms. Donlin:

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 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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170951

Device Name
CardioCel 3D

Indications for Use *(Describe)*
CardioCel 3D is indicated for use as a patch in pericardial closure and the repair of cardiac and vascular defects including intracardiac defects; septal defects, valve and annulus repair; great vessel reconstruction, peripheral vascular reconstruction and suture line buttressing.

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

I. Applicant Information

Date Prepared	March 30, 2017
Submitter	Admedus Regen Pty Ltd
Address	26 Harris Road Malaga, Western Australia 6090 Australia
Establishment Registration	3010805634
Contact Person	Mary E. Donlin Vice President Regulatory Affairs and Compliance
Telephone Number Fax Number	(651) 493-0606 Ext 1008 (651) 528-8042

II. Device Information

Trade Name	CardioCel® 3D
Common Name	Cardiovascular Patch
Classification Name	Intracardiac Patch or Pledget, Biologically Derived
Classification	Class II, 21 CFR § 870.3470
Product Code	PSQ
Predicate Device	CardioCel (K130872)
Device Description	The CardioCel 3D device is a bovine pericardial patch prepared from glutaraldehyde-crosslinked bovine pericardium using the ADAPT® TEP technology. It is a sterile, light yellow to beige colored, moist, pre-cut sheet of acellular collagen. It is offered in a 4 x 6 cm size with a 60° curve.
Indications for Use	CardioCel 3D is indicated for use as a patch in pericardial closure and the repair of cardiac and vascular defects including intracardiac defects; septal defects, valve and annulus repair; great vessel reconstruction, peripheral vascular reconstruction and suture line buttressing.

Comparison to Predicate Device	The predicate device, CardioCel (K130872), was cleared by the FDA for use as a patch in pericardial closure and the repair of cardiac and vascular defects including intracardiac defects; septal defects, valve and annulus repair; great vessel reconstruction, peripheral vascular reconstruction and suture line buttressing. The CardioCel 3D device is identical to the predicate device with respect to intended use, raw materials, tissue processing, sterilization, packaging and principles of operation. Whereas CardioCel is offered in a flat sheet configuration, the manufacturing change implemented during crosslinking enables CardioCel 3D to hold a curved shape.
Summary of Verification and Validation	Verification and validation testing was conducted on CardioCel 3D including dimensional verification, crosslink stability, tensile testing, and burst pressure testing. A risk assessment included evaluation of biocompatibility, sterility, packaging, and shelf life. The results demonstrated that the design outputs of the modified device meet the design inputs in conformance with established design controls.
Conclusion	The accumulated technical information, intended use, and laboratory verification tests demonstrate that CardioCel 3D is substantially equivalent to the currently marketed predicate device.