DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 14, 2016

Admedus Regen Pty Ltd
% Ms. Mary Donlin
Director Regulatory Affairs and Compliance
Admedus Corporation
860 Blue Gentian Road, Ste 295
Eagan, Minnesota 55121

Re: K162579
Trade/Device Name: VascuCel
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: DXZ
Dated: September 14, 2016
Received: September 15, 2016

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 yours,

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)*
~~K16XXXX~~ K162579

Device Name
VascuCel

Indications for Use *(Describe)*
VascuCel is indicated as a patch in great vessel repair, 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.

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5. 510(k) SUMMARY of Safety and Effectiveness

(In accordance with SMDA of 1990 and pursuant with 21 CFR 807.92)

I. Applicant Information:

Date Prepared:	September 14, 2016
Submitter:	Admedus Regen Pty Ltd
Address:	26 Harris Road Malaga, Western Australia 6090 Australia
Establishment Registration No.	3010805634
Contact Person:	Mary E. Donlin Director Regulatory Affairs and Compliance
Telephone Number:	(651) 493-0606 Ext 1008
Fax Number:	(651) 528-8042

II. Device Information:

Trade Name:	VascuCel™
Common Name:	Cardiovascular Patch
Classification Name:	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE
Classification:	Class II, 21 CFR § 870.3470
Product Code:	DXZ
Predicate Device:	K130872 CardioCel
Predicate Device Intended Use:	CardioCel 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.
Device Description:	The VascuCel 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 2 x 8 cm size and a 0.8 x 8 cm size.

Intended Use:	VascuCel is indicated as a patch in great vessel repair, peripheral vascular reconstruction and suture line buttressing.
Contraindications:	VascuCel is not designed, sold or intended for use except as indicated. The use of a tissue bioprosthesis must be considered on an individual patient basis.
Comparison to Predicate Device:	CardioCel was cleared by the FDA (K130872) 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 additional sizes added to the existing CardioCel product line are within the current product specification range for CardioCel. The minor change to the dimensions of the device (from 5 cm x 8 cm to 2 cm x 8 cm and 0.8cm x 8 cm respectively) is also included in this submission. The purpose of the dimensional change is to manufacture a device that meets the current needs of the surgeon and to reduce the free hand trimming of the device during the surgical procedure. The primary purpose for this submission is to modify the indication for use from a general to specific indication to denote the use as a patch for great vessel reconstruction, peripheral vascular reconstruction and suture line buttressing.
Test Data:	The safety and effectiveness of bovine pericardial patches for the reconstruction and repair of cardiac and vascular anatomy is well established in clinical literature and is the current standard of care in clinical practice. The verification and validation testing conducted on CardioCel has demonstrated that the device is safe and effective for the proposed indication for use as a patch for peripheral vascular reconstruction and suture line buttressing. Clinical data demonstrating the acute safety of VascuCel is also provided to support the proposed specific indication.
Summary:	The accumulated technical information, intended use, laboratory verification tests and clinical performance data that was performed on CardioCel as provided in K130872, demonstrates that VascuCel is substantially equivalent to the currently marketed predicate device.