April 3, 2020

Admedus Regen Pty Ltd
Diana Upp
Sr. Regulatory Affairs Specialist
860 Blue Gentian Road, Suite 340
Eagan, Minnesota 55121

Re: K200566
Trade/Device Name: ADAPT® Tissue
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: February 21, 2020
Received: March 4, 2020

Dear Diana Upp:

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,

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K200566

Device Name
ADAPT® Tissue

Indications for Use *(Describe)*
The ADAPT® Tissue is indicated for use as a patch in the repair of cardiac defects including intracardiac defects, septal defects, valve and annulus repair.

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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K200566 510(k) Summary

I. Applicant Information:

Date Prepared: March 27, 2020

Submitter: Admedus Regen PTY LTD

Address: 26 Harris Road
Malaga Western Australia 6080

Establishment Registration No. 3010805634

Contact Person: Kiran Bhirangi, MBBS FRCS (I)

Telephone Number: +1 651-900-2151

II. Device Information:

Trade Name: ADAPT® Tissue

Common Name: Cardiovascular Patch

Classification Name: Intracardiac Patch or Pledget, Biologically Derived

Classification: Class II, 21 CFR § 870.3470

Product Code: PSQ

Predicate Devices: CardioCel (K130872) and VascuCel (K162579)

Device Description: The ADAPT® Tissue medical 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. The products range in size from 4cm^2 to 84cm^2 and can range in thickness from 0.25-0.80mm.

Intended Use: The ADAPT® Tissue is indicated for use as a patch in the repair of cardiac defects including intracardiac defects, septal defects, valve and annulus repair.

Comparative Analysis: The proposed and predicate devices are identical in design and manufacturing. The proposed device represents a labeling change only. Both the subject and predicate devices are manufactured from glutaraldehyde fixed bovine pericardium using the ADAPT® TEP technology.

Table 5-1 below reveals key similarities and is the basis for substantial equivalence of the ADAPT® Tissue to the predicate devices.

Table 5-1: Predicate Device(s) Comparison Chart

Description	ADAPT® Tissue (Proposed Device)	VascuCel (Predicate Device)	CardioCel (Primary Predicate Device)	Comparison
Regulatory Class	II	II	II	Substantially equivalent
510(k) No.	New	K162579	K130872	
Classification Name	Intracardiac Patch or Pledget	Intracardiac Patch or Pledget	Intracardiac Patch or Pledget	Substantially equivalent
CFR Section	21 CFR 870.3470	21 CFR 870.3470	21 CFR 870.3470	
Device Name	ADAPT® Tissue	VascuCel	CardioCel	
Trade/Common Name	ADAPT® Tissue	VascuCel	CardioCel	
Manufacturer	Admedus Regen PTY LTD	Admedus Regen PTY LTD	Admedus Regen PTY LTD	Same
Device Description	The ADAPT® Tissue medical 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.	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.	The CardioCel device is a cardiovascular patch prepared from glutaraldehyde-crosslinked bovine pericardium using the ADAPT® TEP technology. It is a sterile, light yellow or beige colored, moist, pre-cut, flat sheet of acellular collagen.	Substantially equivalent
Intended Use / Indications for Use	The ADAPT® Tissue is indicated for use as a patch in the repair of cardiac defects including intracardiac defects, septal defects, valve and annulus repair.	VascuCel is indicated as a patch in great vessel repair, peripheral vascular reconstruction and suture line buttressing.	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.	Substantially equivalent – the indication for use statement of the proposed device is a subset of the predicate device indication for use

Description	ADAPT® Tissue (Proposed Device)	VascuCel (Predicate Device)	CardioCel (Primary Predicate Device)	Comparison
Intended Population	Patients who require repair of cardiac defects including intracardiac defects, septal defects, valve and annulus repair.	Patients who require great vessel repairs; vascular reconstruction and suture-line buttressing	Patients with intracardiac and cardiovascular defects requiring repair (pediatric and adult groups)	Substantially equivalent
Clinical Setting	In-hospital (bioimplant that is surgically implanted)	In-hospital (bioimplant that is surgically implanted)	In-hospital (bioimplant that is surgically implanted during open heart surgery)	
Anatomical Sites	Cardiovascular	Peripheral Vasculature	Cardiovascular	
Materials	Bovine Pericardium	Bovine Pericardium	Bovine Pericardium	
Design and Scientific Principles	Glutaraldehyde fixed bovine pericardium using ADAPT® TEP technology	Glutaraldehyde fixed bovine pericardium using ADAPT® TEP technology	Glutaraldehyde fixed bovine pericardium using ADAPT® TEP technology	
Performance	A long-term implant for the repair of cardiac defects	A long-term implant for the great vessel repair and peripheral vascular reconstruction	A long-term implant for the repair of cardiovascular defects	Substantially equivalent
Sterilization Method	Propylene oxide	Propylene oxide	Propylene oxide	
Biocompatibility	Biocompatible; meeting the requirements of ISO 10993	Biocompatible; meeting the requirements of ISO 10993	Biocompatible; meeting the requirements of ISO 10993	Substantially equivalent

Performance Evaluation:

The nonclinical testing performed in support of the general intended use for CardioCel also demonstrates substantial equivalence of the specific ADAPT® Tissue indication for the repair of cardiac defects including intracardiac defects, septal defects, valve and annulus repair. The CardioCel and ADAPT Tissue devices are identical in design and manufacturing. No additional testing was conducted to support the labeling change that is the purpose of this submission.

Summary:	The results from design verification and design validation studies performed in support of CardioCel and VascuCel have been found to directly support performance of the ADAPT® Tissue. Therefore, the ADAPT® Tissue is substantially equivalent to the predicate devices.