

**K162579 VascuCel**Oct 14, 2016  
29 days to decisionK162579 · Product code: **DXZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k162579/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Sep 15, 2016
Decision date	Oct 14, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Admedus Regen Pty, Ltd.</b>
Location	Malaga, AU
Contact	Mary E. Donlin
510(k) history	3 submissions · 3 cleared · 2016-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162579/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 19, 2026