

K170951 CardioCel 3DApr 28, 2017
28 days to decisionK170951 · Product code: **PSQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k170951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intracardiac Patch Or Pledget, Biologically Derived (PSQ)
Date received	Mar 31, 2017
Decision date	Apr 28, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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