

K200566 ADAPT TissueApr 3, 2020
30 days to decisionK200566 · Product code: **PSQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k200566/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intracardiac Patch Or Pledget, Biologically Derived (PSQ)
Date received	Mar 4, 2020
Decision date	Apr 3, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200566/> Data sourced from FDA 510(k) public records (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. - Generated June 19, 2026