

**K112683 SMI CARDIOVASCULAR PACH**Dec 14, 2011  
90 days to decisionK112683 · Product code: **DXZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k112683/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Sep 15, 2011
Decision date	Dec 14, 2011
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Solimas Medical, Inc.</b>
Location	Sunny Vale, CA, US
Contact	MICHEAL KOLBE
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112683/> 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 15, 2026