

**K130872 CARDIOCEL**Jan 30, 2014  
307 days to decisionK130872 · Product code: **DXZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k130872/>**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	Mar 29, 2013
Decision date	Jan 30, 2014
Days to decision	307 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Celxcel Pty, Ltd.</b>
Location	Rockville, MD, US
Contact	CHRISTOPHER SLOAN
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130872/> 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 7, 2026