

**K082139 EDWARDS BOVINE PERICARDIAL PATCH, MODEL 4700**Oct 23, 2008  
86 days to decisionK082139 · Product code: **DXZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k082139/>**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	Jul 29, 2008
Decision date	Oct 23, 2008
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edwards Lifesciences, LLC</b>
Location	Irvine, CA, US
Contact	DARYL RICHARDSON
Website	<a href="https://www.edwards.com">https://www.edwards.com</a>
510(k) history	135 submissions · 129 cleared · 1979-2026

Edwards Lifesciences, LLC is a global structural heart innovation company headquartered in Irvine, California. The company specializes in advanced medical devices for cardiovascular disease management. Edwards Lifesciences has established a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1979. The company's portfolio is dominated by Cardiovascular devices, which represent 88% of all submissions. The latest clearance was received in 2026, demonstrating continued active development and regulatory engagement. Recent clea...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k082139/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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