

**K090637 CARDIO-WRAP**Jan 7, 2010  
303 days to decisionK090637 · Product code: **DXZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k090637/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Mar 10, 2009
Decision date	Jan 7, 2010
Days to decision	303 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mast Biosurgery USA, Inc.</b>
Location	San Diego, CA, US
Contact	KENNETH K KLEINHENZ
510(k) history	4 submissions · 3 cleared · 2005-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090637/> 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 21, 2026