

**K012053 DIAMEDIX IS-ANTI-CARDIOLIPIN SCREEN TEST SYSTEM**Aug 20, 2001  
49 days to decisionK012053 · Product code: **MID** · Immunology  
Source: <https://www.510kdatabase.net/k012053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jul 2, 2001
Decision date	Aug 20, 2001
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diamedix Corp.</b>
Location	Miami, FL, US
Contact	LYNNE STIRLING
510(k) history	68 submissions · 68 cleared · 1986-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012053/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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