

K012449 DIAMEDIX IS-ANTI-CARDIOLIPIN IGG/IGM TEST SYSTEMOct 26, 2001
86 days to decisionK012449 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k012449/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Aug 1, 2001
Decision date	Oct 26, 2001
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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