

**K013628 DIAMEDIX IS-ANTI-B2 GLYCOPROTEIN I IGG/IGM
TEST SYSTEM**Dec 21, 2001
46 days to decisionK013628 · Product code: **MSV** · Immunology
Source: <https://www.510kdatabase.net/k013628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV)
Date received	Nov 5, 2001
Decision date	Dec 21, 2001
Days to decision	46 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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