

**K920401 IMMUNOWELL CARDIOLIPIN ANTIBODY (IGM) TEST**Aug 20, 1992  
204 days to decisionK920401 · Product code: **MID** · Immunology  
Source: <https://www.510kdatabase.net/k920401/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jan 29, 1992
Decision date	Aug 20, 1992
Days to decision	204 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>General Biometrics, Inc.</b>
Location	San Diego, CA, US
Contact	BRYAN L KIEHL
510(k) history	23 submissions · 23 cleared · 1989-1992

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