

**K001981 DIASTAT ANTI-CARDIOLIPIN IGA, MODEL FCAR 500**Aug 21, 2000  
53 days to decisionK001981 · Product code: **MID** · Immunology  
Source: <https://www.510kdatabase.net/k001981/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jun 29, 2000
Decision date	Aug 21, 2000
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Axis-Shield , Ltd.</b>
Location	Dundee, GB
Contact	EILEEN MCCAFFERTY
510(k) history	2 submissions · 2 cleared · 2000-2005

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