

**K020156 DIASTAT TOTAL ANTI-CARDIOLIPIN, MODEL FCAR  
100T**Mar 6, 2002  
48 days to decisionK020156 · Product code: **MID** · Immunology  
Source: <https://www.510kdatabase.net/k020156/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jan 17, 2002
Decision date	Mar 6, 2002
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Axis-Shield Diagnostics, Ltd.</b>
Location	Dundee, GB
Contact	EILEEN MCCAFFERTY
Website	<a href="http://www.axis-shield.com/">http://www.axis-shield.com/</a>
510(k) history	24 submissions · 24 cleared · 2002-2026

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