

**K992449 AUTOSTAT II ANTI-CARDIOLIPIN IGM ELISA**Nov 24, 1999  
125 days to decisionK992449 · Product code: **MID** · Immunology  
Source: <https://www.510kdatabase.net/k992449/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jul 22, 1999
Decision date	Nov 24, 1999
Days to decision	125 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cogent Diagnostics , Ltd.</b>
Location	Dunblane, Fk15 9ep, GB
Contact	DANIELLE M KNIGHT
510(k) history	31 submissions · 31 cleared · 1992-2000

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