

K992440 AUTOSTAT II ANTI-CARDIOLIPIN IGG ELISASep 21, 1999
61 days to decisionK992440 · Product code: **MID** · Immunology
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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	Sep 21, 1999
Days to decision	61 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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