

K993085 AUTOSTAT II ANTI-CARDIOLIPIN SCREEN ELISAFeb 1, 2000
139 days to decisionK993085 · Product code: **MID** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Sep 15, 1999
Decision date	Feb 1, 2000
Days to decision	139 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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