

K983921 AUTOSTAT II ENA SCREEN ELISADec 28, 1998
54 days to decisionK983921 · Product code: LLL · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Nov 4, 1998
Decision date	Dec 28, 1998
Days to decision	54 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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