

K990626 AUTOSTAT II ANTI-SS-B/LA ELISAApr 28, 1999
62 days to decisionK990626 · 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	Feb 25, 1999
Decision date	Apr 28, 1999
Days to decision	62 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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