

K990625 AUTOSTAT II ANTI-SM ELISAApr 28, 1999
62 days to decisionK990625 · Product code: **LKP** · Immunology
Source: <https://www.510kdatabase.net/k990625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
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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