

K983655 AUTOSTAT II ANA SCREEN ELISAJan 28, 1999
101 days to decisionK983655 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k983655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Oct 19, 1998
Decision date	Jan 28, 1999
Days to decision	101 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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