

**K003057 AUTOSTAT II ENA-4 PROFILE ELISA**Oct 13, 2000  
11 days to decisionK003057 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k003057/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Oct 2, 2000
Decision date	Oct 13, 2000
Days to decision	11 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cogent Diagnostics , Ltd.</b>
Location	Dunblane, Fk15 9ep, GB
Contact	DANIELLE KNIGHT
510(k) history	31 submissions · 31 cleared · 1992-2000

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