

K991942 AUTOSTAT II ANTI-GPC ELISA, HY.TEC ANTI-GPC ELISAAug 24, 1999
76 days to decisionK991942 · Product code: **MLE** · Immunology
Source: <https://www.510kdatabase.net/k991942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Antiparietal Cell Antibody, Antigen, Control (MLE)
Date received	Jun 9, 1999
Decision date	Aug 24, 1999
Days to decision	76 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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