

**K994338 AUTOSTAT II RHEUMATOID FACTOR IGM ELISA**Feb 3, 2000  
42 days to decisionK994338 · Product code: **DHR** · Immunology  
Source: <https://www.510kdatabase.net/k994338/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Dec 23, 1999
Decision date	Feb 3, 2000
Days to decision	42 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 M KNIGHT
510(k) history	31 submissions · 31 cleared · 1992-2000

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