

**K002215 AUTOSTAT II ANTI-MYELOPEROXIDASE (MPO) ELISA**Sep 28, 2000  
66 days to decisionK002215 · Product code: **MOB** · Immunology  
Source: <https://www.510kdatabase.net/k002215/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Jul 24, 2000
Decision date	Sep 28, 2000
Days to decision	66 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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