

**K952567 AUTOSTATTMII ANTI-DSDNA**Mar 4, 1997  
638 days to decisionK952567 · Product code: **LRM** · Immunology  
Source: <https://www.510kdatabase.net/k952567/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM) |
| Date received         | Jun 5, 1995  |
| Decision date         | Mar 4, 1997  |
| Days to decision      | 638 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        | JIM WESTON                              |
| 510(k) history | 31 submissions · 31 cleared · 1992-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k952567/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026