

**K923371 AUTOSTAT ANTI-THYROID MICROSSOMAL**Sep 22, 1992  
75 days to decisionK923371 · Product code: **JNL** · Immunology  
Source: <https://www.510kdatabase.net/k923371/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | Immunochemical, Thyroglobulin Autoantibody (JNL) |
| Date received         | Jul 9, 1992                                      |
| Decision date         | Sep 22, 1992                                     |
| Days to decision      | 75 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        | MCGREGOR                                |
| 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/k923371/> 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 29, 2026