

**K921183 DIASTAT ANTI-MITOCHONDRIAL ANTIBODY KIT**Jun 19, 1992  
102 days to decisionK921183 · Product code: **DBM** · Immunology  
Source: <https://www.510kdatabase.net/k921183/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Antimitochondrial Antibody, Indirect Immunofluorescent, Antigen, Control (DBM) |
| Date received         | Mar 9, 1992  |
| Decision date         | Jun 19, 1992   |
| Days to decision      | 102 days   |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shield Diagnostics, Ltd.</b>         |
| Location       | Scotland, KN                            |
| Contact        | GEORGE ZAJICEK                          |
| 510(k) history | 27 submissions · 27 cleared · 1990-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921183/> 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 28, 2026