

**K041002 FIDIS CELIAC**Sep 24, 2004  
158 days to decisionK041002 · Product code: **MST** · Immunology  
Source: <https://www.510kdatabase.net/k041002/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Antibodies, Gliadin (MST)          |
| Date received         | Apr 19, 2004                       |
| Decision date         | Sep 24, 2004                       |
| Days to decision      | 158 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Biomedical Diagnostics S.A.</b>    |
| Location       | Marne-La-Vallee, Cedex 2, FR          |
| Contact        | PASCALE LAROCHE                       |
| 510(k) history | 1 submissions · 1 cleared · 2004-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041002/> 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