

**K982714 BAYER IMMUNO 1 SYSTEM FERRITIN ASSAY**Oct 22, 1998  
79 days to decisionK982714 · Product code: **DBF** · Immunology  
Source: <https://www.510kdatabase.net/k982714/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Ferritin, Antigen, Antiserum, Control (DBF) |
| Date received         | Aug 4, 1998                                 |
| Decision date         | Oct 22, 1998                                |
| Days to decision      | 79 days                                     |
| Third-party review    | No  |
| Summary / Statement   | Summary                                     |

**APPLICANT**

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|----------------|---|
| Company        | <b>Bayer Corp.</b>                      |
| Location       | Elkhart, IN, US                         |
| Contact        | GABRIEL J MURACA, JR.                   |
| 510(k) history | 96 submissions · 96 cleared · 1989-2003 |

Bayer Corp. is the American subsidiary of Bayer AG, headquartered in Whippany, New Jersey. The company operates 40 fully consolidated subsidiaries across 19 states. Bayer Corp. received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory activity spans from 1989 to 2003, with a primary focus on chemistry devices and immunology assays. Notable cleared devices include the ASCENSIA BREEZE BLOOD GLUCOSE METER, CLINITEST PREGNANCY TEST, and the ADVIA CENTAUR immunoassay system. This represents a historical regulatory rec...

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