

**K973202 MODIFICATION OF OPUS FERRITIN TEST SYSTEM**Sep 12, 1997  
66 days to decisionK973202 · Product code: **DBF** · Immunology  
Source: <https://www.510kdatabase.net/k973202/>**SUBMISSION DETAILS**

---

|                       |                                             |
|-----------------------|---------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Ferritin, Antigen, Antiserum, Control (DBF) |
| Date received         | Jul 8, 1997                                 |
| Decision date         | Sep 12, 1997                                |
| Days to decision      | 66 days                                     |
| Third-party review    | No                                          |
| Summary / Statement   | Summary                                     |

**APPLICANT**

---

|                |                                           |
|----------------|-------------------------------------------|
| Company        | <b>Behring Diagnostics, Inc.</b>          |
| Location       | Mchenry, IL, US                           |
| Contact        | Ruth Forstadt                             |
| 510(k) history | 145 submissions · 145 cleared · 1976-1997 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973202/> 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