

**K974825 BOEHRINGER MANNHEIM C.F.A.S. - HDL/LDL-C-PLUS**Jan 30, 1998  
37 days to decisionK974825 · Product code: **JIX** · Chemistry  
Source: <https://www.510kdatabase.net/k974825/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Calibrator, Multi-analyte Mixture (JIX) |
| Date received         | Dec 24, 1997                            |
| Decision date         | Jan 30, 1998                            |
| Days to decision      | 37 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Boehringer Mannheim Corp.</b>          |
| Location       | Mchenry, IL, US                           |
| Contact        | EDWARD R KIMMELMAN                        |
| 510(k) history | 340 submissions · 340 cleared · 1976-1999 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974825/> 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 May 22, 2026