

**K964693 ELECSYS FSH ASSAY**Dec 16, 1996  
24 days to decisionK964693 · Product code: **CGJ** · Chemistry  
Source: <https://www.510kdatabase.net/k964693/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | Radioimmunoassay, Follicle-stimulating Hormone (CGJ) |
| Date received         | Nov 22, 1996   |
| Decision date         | Dec 16, 1996   |
| Days to decision      | 24 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964693/> 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