

**K965109 ELECSYS ESTRADIOL ASSAY**Feb 18, 1997  
60 days to decisionK965109 · Product code: **CHP** · Chemistry  
Source: <https://www.510kdatabase.net/k965109/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Radioimmunoassay, Estradiol (CHP)  |
| Date received         | Dec 20, 1996                       |
| Decision date         | Feb 18, 1997                       |
| Days to decision      | 60 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Boehringer Mannheim Corp.</b>          |
| Location       | Mchenry, IL, US                           |
| Contact        | Yvette Lloyd                              |
| 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/k965109/> 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