

**K982948 ELECSYS PSA, MODEL # ELECSYS 1010**Oct 27, 1998  
67 days to decisionK982948 · Product code: **LTJ** · Immunology  
Source: <https://www.510kdatabase.net/k982948/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                       |
| Submission type       | Traditional  |
| Device classification | Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ) |
| Date received         | Aug 21, 1998   |
| Decision date         | Oct 27, 1998   |
| Days to decision      | 67 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Boehringer Mannheim Corp.</b>          |
| Location       | Mchenry, IL, US                           |
| Contact        | PRISCILLA A HAMILL                        |
| 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/k982948/> 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