

**K935502 EVENT TEST STRIP HCG**Jan 27, 1994  
72 days to decisionK935502 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k935502/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received         | Nov 16, 1993                                  |
| Decision date         | Jan 27, 1994                                  |
| Days to decision      | 72 days                                       |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Boehringer Mannheim Italia Spa</b> |
| Location       | Simi Valley, CA, US                   |
| Contact        | CLEVE W LAIRD                         |
| 510(k) history | 3 submissions · 3 cleared · 1994-1996 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935502/> 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 July 1, 2026