

**K955266 ACCUSTAT HCG SERUM DILUENT REAGENT OR  
EVENT SERUM DILUENT**Feb 29, 1996  
106 days to decisionK955266 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k955266/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received         | Nov 15, 1995                                  |
| Decision date         | Feb 29, 1996                                  |
| Days to decision      | 106 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 LAIR                          |
| 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/k955266/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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