

**K984425 MODIFICATION OF PRECISET SERUM PROTEINS  
CALIBRATOR**Jan 20, 1999  
40 days to decisionK984425 · Product code: JIX · Chemistry  
Source: <https://www.510kdatabase.net/k984425/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Dec 11, 1998
Decision date	Jan 20, 1999
Days to decision	40 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/k984425/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 22, 2026