

**K981281 ELECSYS CALCHECK FERRITIN**Apr 24, 1998  
16 days to decisionK981281 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k981281/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Apr 8, 1998
Decision date	Apr 24, 1998
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics GmbH</b>
Location	Mannheim, DE
Contact	PATRICIA M KLIMELY
510(k) history	5 submissions · 5 cleared · 1998-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981281/> 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 21, 2026