

K981278 ELECSYS CALCHECK CA 125IIApr 23, 1998
15 days to decisionK981278 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k981278/>**SUBMISSION DETAILS**

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 23, 1998
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics GmbH
Location	Mannheim, DE
Contact	Patricia M Klimley
510(k) history	5 submissions · 5 cleared · 1998-2026

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