

**K970459 ELECSYS CALCHECK CEA**Mar 6, 1997  
28 days to decisionK970459 · Product code: **JJX** · Immunology  
Source: <https://www.510kdatabase.net/k970459/>**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	Feb 6, 1997
Decision date	Mar 6, 1997
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boehringer Mannheim Corp.</b>
Location	Mchenry, IL, US
Contact	Patricia M Klimley
510(k) history	340 submissions · 340 cleared · 1976-1999

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