

K974383 ELECSYS CALCHECK VITAMIN B12Dec 8, 1997
17 days to decisionK974383 · Product code: **JJX** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Nov 21, 1997
Decision date	Dec 8, 1997
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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