

K970458 ELECSYS CALCHECK PSAMar 6, 1997
28 days to decisionK970458 · Product code: **JJX** · Immunology
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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

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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