

K970146 ELECSYS CALCHECK TESTOSTERONEJan 30, 1997
15 days to decisionK970146 · 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	Jan 15, 1997
Decision date	Jan 30, 1997
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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