

**K964368 ELECSYS CEA ASSAY**Jun 16, 1997  
227 days to decisionK964368 · Product code: **JIT** · Immunology  
Source: <https://www.510kdatabase.net/k964368/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Nov 1, 1996
Decision date	Jun 16, 1997
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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