

**K964694 ELECSYS LH ASSAY**Jan 24, 1997  
63 days to decisionK964694 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k964694/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Nov 22, 1996
Decision date	Jan 24, 1997
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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