

K980240 ELECSYS CA 125II ON THE ELECSYS 1010Mar 25, 1998
61 days to decisionK980240 · Product code: **LTK** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Jan 23, 1998
Decision date	Mar 25, 1998
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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