

K972162 ELECSYS CA 125 IIMar 18, 1998
282 days to decisionK972162 · Product code: LTK · Immunology
Source: <https://www.510kdatabase.net/k972162/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Jun 9, 1997
Decision date	Mar 18, 1998
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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