

K964185 IMX CA 125Nov 4, 1997
379 days to decisionK964185 · Product code: **LTK** · Immunology
Source: <https://www.510kdatabase.net/k964185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Oct 21, 1996
Decision date	Nov 4, 1997
Days to decision	379 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Diagnostics
Location	Mountain View, CA, US
Contact	JOY C SONSALLA
510(k) history	28 submissions · 28 cleared · 1981-1997

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