

K990431 AIA-PACK CA 125Jun 3, 1999
112 days to decisionK990431 · Product code: **LTK** · Immunology
Source: <https://www.510kdatabase.net/k990431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Feb 11, 1999
Decision date	Jun 3, 1999
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tosoh Medics, Inc.
Location	Washington, DC, US
Contact	JUDITH E LOEBEL
510(k) history	41 submissions · 41 cleared · 1990-2002

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