

**K023891 ST AIA-PACK CA 125 ENZYME IMMUNOASSAY**Dec 6, 2002  
14 days to decisionK023891 · Product code: **LTK** · Immunology  
Source: <https://www.510kdatabase.net/k023891/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Nov 22, 2002
Decision date	Dec 6, 2002
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tosoh Medics, Inc.</b>
Location	Washington, DC, US
Contact	LOIS NAKAYAMA
510(k) history	41 submissions · 41 cleared · 1990-2002

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