

K023894 ST AIA-PACK AFP ENZYME IMMUNOASSAYDec 17, 2002
25 days to decisionK023894 · Product code: **LOJ** · Immunology
Source: <https://www.510kdatabase.net/k023894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Kit, Test,alpha-fetoprotein For Testicular Cancer (LOJ)
Date received	Nov 22, 2002
Decision date	Dec 17, 2002
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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