

K981282 ELECSYS AFPMay 1, 1998
23 days to decisionK981282 · Product code: **LOJ** · Immunology
Source: <https://www.510kdatabase.net/k981282/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test,alpha-fetoprotein For Testicular Cancer (LOJ)
Date received	Apr 8, 1998
Decision date	May 1, 1998
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics GmbH
Location	Mannheim, DE
Contact	Patricia M Klimley
510(k) history	5 submissions · 5 cleared · 1998-2026

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