

**K973351 ELECSYS AFP**Nov 21, 1997  
77 days to decisionK973351 · Product code: **LOJ** · Immunology  
Source: <https://www.510kdatabase.net/k973351/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test,alpha-fetoprotein For Testicular Cancer (LOJ)
Date received	Sep 5, 1997
Decision date	Nov 21, 1997
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boehringer Mannheim Corp.</b>
Location	Mchenry, IL, US
Contact	Patricia M Klimley
510(k) history	340 submissions · 340 cleared · 1976-1999

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