

**K981354 ACCESS AFP REAGENTS ON THE ACCESS  
IMMUNOASSAY ANALYZER MODEL NUMBER 33211**May 1, 1998  
17 days to decisionK981354 · Product code: LOJ · Immunology  
Source: <https://www.510kdatabase.net/k981354/>**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	Apr 14, 1998
Decision date	May 1, 1998
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman Instruments, Inc.</b>
Location	Mchenry, IL, US
Contact	ELLEN M VOSS
Website	<a href="https://www.beckman.com">https://www.beckman.com</a>
510(k) history	281 submissions · 281 cleared · 1976-1998

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