

**K964506 ROCHE COBAS AMPLICOR ANALYZER**May 21, 1997  
194 days to decisionK964506 · Product code: **JJF** · Chemistry  
Source: <https://www.510kdatabase.net/k964506/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Chemistry, Micro, For Clinical Use (JJF)
Date received	Nov 8, 1996
Decision date	May 21, 1997
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Molecular Systems, Inc.</b>
Location	Somerville, NJ, US
Contact	ALEX WESOLOWSKI
510(k) history	51 submissions · 48 cleared · 1993-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964506/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026