

**K033501 MODIFICATION TO CALIBRATOR FOR AUTOMATIC SYSTEMS (CFAS)**Nov 20, 2003  
15 days to decisionK033501 · Product code: JIX · Chemistry  
Source: <https://www.510kdatabase.net/k033501/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Nov 5, 2003
Decision date	Nov 20, 2003
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	SHERRI L COENEN
510(k) history	264 submissions · 263 cleared · 1999-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033501/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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