

**K011658 CALIBRATOR FOR AUTOMATED SYSTEMS (C.F.A.S.)  
LIPIDS**Jul 31, 2001  
63 days to decisionK011658 · Product code: JIX · Chemistry  
Source: <https://www.510kdatabase.net/k011658/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	May 29, 2001
Decision date	Jul 31, 2001
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rochdiag</b>
Location	Indianapolis, IN, US
Contact	HELEN T TORNEY
510(k) history	3 submissions · 3 cleared · 2001-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011658/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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