

**K111952 ACCESS FOLATE CALIBRATORS ON THE ACCESS  
IMMUNOASSAY SYSTEMS MODEL A98033**Aug 19, 2011  
39 days to decisionK111952 · Product code: JIT · Chemistry  
Source: <https://www.510kdatabase.net/k111952/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Jul 11, 2011
Decision date	Aug 19, 2011
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beckman Coulter, Inc.</b>
Location	Chaska, MN, US
Contact	KERRIE S OETTER
Website	<a href="https://www.beckmancoulter.com">https://www.beckmancoulter.com</a>
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111952/> 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 18, 2026