

**K033009 ROCHE DIAGNOSTICS COBAS INTEGRA ALBUMIN  
GEN. 2**Oct 16, 2003  
20 days to decisionK033009 · Product code: **CIX** · Chemistry  
Source: <https://www.510kdatabase.net/k033009/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bromcresol Green Dye-binding, Albumin (CIX)
Date received	Sep 26, 2003
Decision date	Oct 16, 2003
Days to decision	20 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/k033009/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 9, 2026