

**K823575 COBAS STANDARDS FOR ALBUMIN**Jan 7, 1983  
32 days to decisionK823575 · Product code: **CIX** · Chemistry  
Source: <https://www.510kdatabase.net/k823575/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bromcresol Green Dye-binding, Albumin (CIX)
Date received	Dec 6, 1982
Decision date	Jan 7, 1983
Days to decision	32 days
Third-party review	No

**APPLICANT**

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Company	<b>Hoffmann-La Roche, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.roche.com">https://www.roche.com</a>
510(k) history	49 submissions · 49 cleared · 1976-1985

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k823575/>; 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 29, 2026