

**K193001 Albumin BCP**Dec 19, 2019  
52 days to decisionK193001 · Product code: **CJW** · Chemistry  
Source: <https://www.510kdatabase.net/k193001/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bromocresol Purple Dye-binding, Albumin (CJW)
Date received	Oct 28, 2019
Decision date	Dec 19, 2019
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SENTINEL CH. SpA</b>
Location	Milano, IT
Contact	Patricia Dupe
510(k) history	12 submissions · 12 cleared · 2007-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193001/> 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 May 26, 2026