

**K191245 Yumizen C1200 ALP, Yumizen C1200 Albumin**Aug 30, 2019  
113 days to decisionK191245 · Product code: **CJE** · Chemistry  
Source: <https://www.510kdatabase.net/k191245/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	May 9, 2019
Decision date	Aug 30, 2019
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>HORIBA ABX SAS</b>
Location	Montpellier Cedex 4, FR
Contact	Caroline Ferrer
510(k) history	17 submissions · 17 cleared · 2009-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191245/> 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