

**K912201 PACKS-4 (TM) ANALYZER**Aug 16, 1991  
88 days to decisionK912201 · Product code: **JB Y** · Hematology  
Source: <https://www.510kdatabase.net/k912201/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aggregometer, Platelet, Photo-optical Scanning (JB Y)
Date received	May 20, 1991
Decision date	Aug 16, 1991
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912201/> 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 14, 2026