

**K913384 COLUMNMATE(TM) BETA-THAL CAT. NO. 4515**Dec 17, 1991  
141 days to decisionK913384 · Product code: **JPD** · Hematology  
Source: <https://www.510kdatabase.net/k913384/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A2 Quantitation (JPD)
Date received	Jul 29, 1991
Decision date	Dec 17, 1991
Days to decision	141 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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