

K923317 COLUMNMATE BETA THAL HBA2 CONTROL-ABNORMALAug 25, 1992
49 days to decisionK923317 · Product code: **JPD** · Hematology
Source: <https://www.510kdatabase.net/k923317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A2 Quantitation (JPD)
Date received	Jul 7, 1992
Decision date	Aug 25, 1992
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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