

**K951943 CHROM Z CHROMOGENIC ASSAYS**Nov 13, 1995  
201 days to decisionK951943 · Product code: **JBQ** · Hematology  
Source: <https://www.510kdatabase.net/k951943/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antithrombin Iii Quantitation (JBQ)
Date received	Apr 26, 1995
Decision date	Nov 13, 1995
Days to decision	201 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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