

K931465 REP ALKALINE HB-15 #3196,-8 #3197,-4 3198Jul 6, 1993
104 days to decisionK931465 · Product code: **JBD** · Hematology
Source: <https://www.510kdatabase.net/k931465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Analysis, Electrophoretic Hemoglobin (JBD)
Date received	Mar 24, 1993
Decision date	Jul 6, 1993
Days to decision	104 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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