

K982426 SPIFE ALKALINE HEMOGLOBINDec 17, 1998
157 days to decisionK982426 · Product code: **JBD** · Hematology
Source: <https://www.510kdatabase.net/k982426/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Analysis, Electrophoretic Hemoglobin (JBD)
Date received	Jul 13, 1998
Decision date	Dec 17, 1998
Days to decision	157 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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