

K800853 A,SA2 LYOPHILIZED HEMO CONTROLApr 29, 1980
14 days to decisionK800853 · Product code: **JBD** · Hematology
Source: <https://www.510kdatabase.net/k800853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Analysis, Electrophoretic Hemoglobin (JBD)
Date received	Apr 15, 1980
Decision date	Apr 29, 1980
Days to decision	14 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k800853/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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