

K800852 HEMESPEC CHECK SETMay 2, 1980
17 days to decisionK800852 · Product code: **KRZ** · Hematology
Source: <https://www.510kdatabase.net/k800852/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator For Hemoglobin And Hematocrit Measurement (KRZ)
Date received	Apr 15, 1980
Decision date	May 2, 1980
Days to decision	17 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/k800852/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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