

K840848 BIOSUREMay 1, 1984
67 days to decisionK840848 · Product code: **JJW** · Hematology
Source: <https://www.510kdatabase.net/k840848/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinalysis Controls (assayed And Unassayed) (JJW)
Date received	Feb 24, 1984
Decision date	May 1, 1984
Days to decision	67 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/k840848/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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