

K801318 HELENA ULTRA SENSITIVE CPK REAGENT/DILUEJul 14, 1980
36 days to decisionK801318 · Product code: **JHX** · Chemistry
Source: <https://www.510kdatabase.net/k801318/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorometric Method, Cpk Or Isoenzymes (JHX)
Date received	Jun 8, 1980
Decision date	Jul 14, 1980
Days to decision	36 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/k801318/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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