

K830978 HELENA BIOSTRIP AMay 13, 1983
45 days to decisionK830978 · Product code: **JMA** · Chemistry
Source: <https://www.510kdatabase.net/k830978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Ascorbic, 2,4-dinitrophenylhydrazine (spectrophotometric) (JMA)
Date received	Mar 29, 1983
Decision date	May 13, 1983
Days to decision	45 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/k830978/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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