

K830979 HELENA BIOSTRIP PHMay 5, 1983
37 days to decisionK830979 · Product code: **CEN** · Chemistry
Source: <https://www.510kdatabase.net/k830979/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dye-indicator, Ph (urinary, Non-quantitative) (CEN)
Date received	Mar 29, 1983
Decision date	May 5, 1983
Days to decision	37 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/k830979/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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