

K782035 HEMESPECJan 17, 1979
42 days to decisionK782035 · Product code: **JJQ** · Chemistry
Source: <https://www.510kdatabase.net/k782035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimeter, Photometer, Spectrophotometer For Clinical Use (JJQ)
Date received	Dec 6, 1978
Decision date	Jan 17, 1979
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k782035/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026