

K801410 HEMOHLOBIN A2 CONTROL-LYOPHILIZEDJul 21, 1980
35 days to decisionK801410 · Product code: **JPD** · Hematology
Source: <https://www.510kdatabase.net/k801410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A2 Quantitation (JPD)
Date received	Jun 16, 1980
Decision date	Jul 21, 1980
Days to decision	35 days
Third-party review	No

APPLICANT

Company	Isolab, Inc.
Location	Mchenry, IL, US
510(k) history	44 submissions · 44 cleared · 1977-1996

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Device record: <https://www.510kdatabase.net/k801410/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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