

K801771 ALPHA-THAL SCREEN 20 TEST KIT & 100 KITJan 16, 1981
172 days to decisionK801771 · Product code: **LGL** · Hematology
Source: <https://www.510kdatabase.net/k801771/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Bart's, Hemoglobin (LGL)
Date received	Jul 28, 1980
Decision date	Jan 16, 1981
Days to decision	172 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/k801771/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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