

**K800794 FAST HEMOGLOBIN CONTROL-LYOPHILIZED**Apr 29, 1980  
20 days to decisionK800794 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k800794/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Apr 9, 1980
Decision date	Apr 29, 1980
Days to decision	20 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k800794/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026