

K904814 GLYC-AFFIN GPDec 26, 1990
63 days to decisionK904814 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k904814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Oct 24, 1990
Decision date	Dec 26, 1990
Days to decision	63 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904814/>; 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 June 29, 2026