

**K905513 GLYC-AFFIN(TM)-GA**Jan 15, 1991  
36 days to decisionK905513 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k905513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Dec 10, 1990
Decision date	Jan 15, 1991
Days to decision	36 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905513/>; 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