

K874749 BINAX EQUATE GLYCOHEMOGLOBINAug 12, 1988
268 days to decisionK874749 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k874749/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Nov 18, 1987
Decision date	Aug 12, 1988
Days to decision	268 days
Third-party review	No

APPLICANT

Company	Binax, Inc.
Location	S. Portland, ME, US
Contact	KELSEY, PHD
510(k) history	30 submissions · 30 cleared · 1986-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k874749/>; 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 21, 2026