

K003280 VARIANT II TOTAL GHBDec 19, 2000
61 days to decisionK003280 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k003280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Oct 19, 2000
Decision date	Dec 19, 2000
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Rad
Location	Mchenry, IL, US
Contact	JACKIE BUCKLEY
Website	http://www.bio-rad.com
510(k) history	319 submissions · 319 cleared · 1976-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003280/> 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 May 14, 2026