

K961311 HEMOCUE B-GLUCOSE SYSTEMAug 23, 1996
141 days to decisionK961311 · Product code: **LFR** · Chemistry
Source: <https://www.510kdatabase.net/k961311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Dehydrogenase, Glucose (LFR)
Date received	Apr 4, 1996
Decision date	Aug 23, 1996
Days to decision	141 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hemocue, Inc.
Location	Potomac, MD, US
Contact	R.J. SLOMOFF
510(k) history	9 submissions · 9 cleared · 1991-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961311/> 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 28, 2026