

K000364 ACCU-CHEK COMPLETE METERFeb 23, 2000
19 days to decisionK000364 · Product code: **LFR** · Chemistry
Source: <https://www.510kdatabase.net/k000364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Glucose Dehydrogenase, Glucose (LFR)
Date received	Feb 4, 2000
Decision date	Feb 23, 2000
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	MIKE FLIS
510(k) history	264 submissions · 263 cleared · 1999-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000364/> 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 9, 2026