

K142089 ACCU-CHEK AVIVA EXPERT SYSTEMDec 17, 2014
138 days to decisionK142089 · Product code: **LFR** · Chemistry
Source: <https://www.510kdatabase.net/k142089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Dehydrogenase, Glucose (LFR)
Date received	Aug 1, 2014
Decision date	Dec 17, 2014
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corporation
Location	Indianapolis, IN, US
Contact	Greg Mondics
510(k) history	6 submissions · 6 cleared · 2007-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142089/> 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 5, 2026