FDA 510(k) Premarket Notification

K142089 ACCU-CHEK AVIVA EXPERT SYSTEM

CLEARED

Dec 17, 2014
138 days to decision

K142089 · 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	Indianpolis, IN, US
Contact	Greg Mondics
510(k) history	6 submissions · 6 cleared · 2007-2015