

**K141928 COBAS C ACETAMINOPHEN GEN.2 ASSAY, ACET2
CALIBRATOR**Nov 25, 2014
132 days to decisionK141928 · Product code: **DKB** · Chemistry
Source: <https://www.510kdatabase.net/k141928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Jul 16, 2014
Decision date	Nov 25, 2014
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Operations (Rdo)
Location	Indianapolis, IN, US
Contact	NOEL K MENCAS
510(k) history	14 submissions · 14 cleared · 2014-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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