

K163633 cobas HbA1c Test, cobas b 101 systemJul 28, 2017
218 days to decisionK163633 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k163633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Dec 22, 2016
Decision date	Jul 28, 2017
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Operations
Location	Indianapolis, IN, US
Contact	Patty Bates
510(k) history	5 submissions · 5 cleared · 2012-2025

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