

**K160571 cobas c513 Analyzer, cobas c13 Tina-quant HbA1cDx
Gen.3 Assay**Dec 19, 2016
294 days to decisionK160571 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k160571/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Feb 29, 2016
Decision date	Dec 19, 2016
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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