

K193053 Tina-quant Hemoglobin A1cDx Gen.3Mar 26, 2020
146 days to decisionK193053 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k193053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Nov 1, 2019
Decision date	Mar 26, 2020
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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