

K161817 Tina-quant Cystatin C Gen.2Jul 27, 2016
26 days to decisionK161817 · Product code: **NDY** · Chemistry
Source: <https://www.510kdatabase.net/k161817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Cystatin C (NDY)
Date received	Jul 1, 2016
Decision date	Jul 27, 2016
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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