

**K080811 TINA-QUANT CYSTATIN C, CALIBRATOR F.A.S.
CYSTATIN C AND CYSTATIN C ANDCYSTATIN C CONTROL
SET**Jun 20, 2008
88 days to decisionK080811 · Product code: **NDY** · Chemistry
Source: <https://www.510kdatabase.net/k080811/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Cystatin C (NDY)
Date received	Mar 24, 2008
Decision date	Jun 20, 2008
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	KERWIN L KAUFMAN
510(k) history	264 submissions · 263 cleared · 1999-2013

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