

K061683 TINA-QUANT MYOGLOBIN GEN.2 TEST SYSTEMJul 21, 2006
36 days to decisionK061683 · Product code: **DDR** · Chemistry
Source: <https://www.510kdatabase.net/k061683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Jun 15, 2006
Decision date	Jul 21, 2006
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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