

K050113 TINA-QUANT IGG GEN.2Feb 8, 2005
21 days to decisionK050113 · Product code: **DEW** · Immunology
Source: <https://www.510kdatabase.net/k050113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igg, Antigen, Antiserum, Control (DEW)
Date received	Jan 18, 2005
Decision date	Feb 8, 2005
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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