

K040435 ROCHE DIAGNOSTICS TINA-QUANT IGA GEN.2Mar 10, 2004
20 days to decisionK040435 · Product code: **CZP** · Immunology
Source: <https://www.510kdatabase.net/k040435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Iga, Antigen, Antiserum, Control (CZP)
Date received	Feb 19, 2004
Decision date	Mar 10, 2004
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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