

**K012361 TINA-QUANT COMPLEMENT C3C TEST SYSTEM**Nov 29, 2001  
127 days to decisionK012361 · Product code: **CZW** · Immunology  
Source: <https://www.510kdatabase.net/k012361/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C3, Antigen, Antiserum, Control (CZW)
Date received	Jul 25, 2001
Decision date	Nov 29, 2001
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	HELEN T TORNEY
510(k) history	264 submissions · 263 cleared · 1999-2013

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