

K012359 TINA-QUANT COMPLEMENT C4 TEST SYSTEMNov 29, 2001
127 days to decisionK012359 · Product code: **DBI** · Immunology
Source: <https://www.510kdatabase.net/k012359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C4, Antigen, Antiserum, Control (DBI)
Date received	Jul 25, 2001
Decision date	Nov 29, 2001
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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