

K013206 TINA-QUANT APOLIPOPROTEIN B VER.2Nov 16, 2001
52 days to decisionK013206 · Product code: **DFC** · Chemistry
Source: <https://www.510kdatabase.net/k013206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Sep 25, 2001
Decision date	Nov 16, 2001
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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