

K113072 TINA-QUANT ALBUMIN GEN.2May 14, 2012
210 days to decisionK113072 · Product code: **DCF** · Toxicology
Source: <https://www.510kdatabase.net/k113072/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Albumin, Antigen, Antiserum, Control (DCF)
Date received	Oct 17, 2011
Decision date	May 14, 2012
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Operations
Location	Indianapolis, IN, US
Contact	PATRICK STIMART
510(k) history	5 submissions · 5 cleared · 2012-2025

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