

**K032535 MODIFICATION TO: ROCHE DIAGNOSTICS TINA-
QUANT RHEUMATOID FACTORS II TEST SYSTEM**Sep 10, 2003
23 days to decisionK032535 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k032535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Aug 18, 2003
Decision date	Sep 10, 2003
Days to decision	23 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032535/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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