

**K002609 TINA-QUANT RHEUMATOID FACTORS II TEST SYSTEM**Sep 5, 2000  
14 days to decisionK002609 · Product code: **DHR** · Immunology  
Source: <https://www.510kdatabase.net/k002609/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Aug 22, 2000
Decision date	Sep 5, 2000
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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