

**K041863 VITROS CHEMISTRY PRODUCTS RF REAGENT,  
VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 16, VITROS  
CHEMISTRY PRODUCTS FS**Sep 20, 2004  
73 days to decisionK041863 · Product code: **DHR** · Immunology  
Source: <https://www.510kdatabase.net/k041863/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Jul 9, 2004
Decision date	Sep 20, 2004
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortho-Clinical Diagnostics, Inc.</b>
Location	Rochester, NY, US
Contact	MARLENE A HANNA
510(k) history	106 submissions · 104 cleared · 1997-2025

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