

K042475 VITROS CHEMISTRY PRODUCTS IGG, IGA AND IGM REAGENTSNov 10, 2004
58 days to decisionK042475 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k042475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Sep 13, 2004
Decision date	Nov 10, 2004
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary
Other names	VITROS CHEMISTRY PRODUCT CALIBRATOR KIT 20; VITROS CHEMISTRY PRODUC

APPLICANT

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

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