

**K121608 VITROS IMMUNODIAGNOSTIC PRODUCTS 25-OH
VITAMIN D TOTAL REAGENT PACK, VITAMIN D TOTAL
CALIBRATORS**Feb 15, 2013
259 days to decisionK121608 · Product code: **MRG** · Chemistry
Source: <https://www.510kdatabase.net/k121608/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Vitamin D (MRG)
Date received	Jun 1, 2012
Decision date	Feb 15, 2013
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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