

**K062123 VITROS CHEMISTRY PRODUCTS COCM REAGENT,
CALBRATOR KIT 26, FS CALBRATOR 1 AND DAT
PERFORMANCE VERIFIERS I, II, III, IV**Nov 16, 2006
114 days to decisionK062123 · Product code: **DIO** · Chemistry
Source: <https://www.510kdatabase.net/k062123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cocaine And Cocaine Metabolites (DIO)
Date received	Jul 25, 2006
Decision date	Nov 16, 2006
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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