

**K071216 VITROS CHEMISTRY PRODUCTS CRSC SLIDES,
VITROS CHEMISTRY PRODUCTS DT CALIBRATOR KIT, MODEL
680 2721, 195 7927**May 25, 2007
23 days to decisionK071216 · Product code: JFY · Chemistry
Source: <https://www.510kdatabase.net/k071216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	May 2, 2007
Decision date	May 25, 2007
Days to decision	23 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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