

**K001310 VITROS CHEMISTRY PRODUCTS CREA SLIDE,
VIRTROS CHEMISTRY PRODUCTS CALIBRATOR KIT 1**May 5, 2000
10 days to decisionK001310 · Product code: JFY · Chemistry
Source: <https://www.510kdatabase.net/k001310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Apr 25, 2000
Decision date	May 5, 2000
Days to decision	10 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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