

**K063591 VITROS CHEMISTRY PRODUCTS CREA
SLIDES,MODEL# 6802584, VITROS CHEMISTRY PRODUCTS
CALIBRATOR KIT 1,MODEL#1882208**Dec 15, 2006
14 days to decisionK063591 · Product code: JFY · Chemistry
Source: <https://www.510kdatabase.net/k063591/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Dec 1, 2006
Decision date	Dec 15, 2006
Days to decision	14 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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