

**K063144 VITROS 5,1 FS CHEMISTRY SYSTEM WITH ENGEN
LABORATORY AUTOMATION SYSTEM**Nov 13, 2006
28 days to decisionK063144 · Product code: **JJE** · Chemistry
Source: <https://www.510kdatabase.net/k063144/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE)
Date received	Oct 16, 2006
Decision date	Nov 13, 2006
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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