

K161140 VITROS Chemistry Products Calibrator Kit 3May 20, 2016
28 days to decisionK161140 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k161140/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Apr 22, 2016
Decision date	May 20, 2016
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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