

K060650 VITROS CHEMISTRY PRODUCTS D%A**1C REAGENT
KIT, MODEL 680 2314**Apr 6, 2006
24 days to decisionK060650 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k060650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 13, 2006
Decision date	Apr 6, 2006
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary
Other names	VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 18, MODEL 680 1702

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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