

**K083680 VITROS CHEMISTRY PRODUCTS K+DT SLIDES:  
VITROS CHEMISTRY PRODUCTS DT CALIBRATOR KIT, MODEL  
K+DT SLIDES: 153 2258**Feb 27, 2009  
77 days to decisionK083680 · Product code: **CEM** · Chemistry  
Source: <https://www.510kdatabase.net/k083680/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Ion Specific, Potassium (CEM)
Date received	Dec 12, 2008
Decision date	Feb 27, 2009
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083680/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 23, 2026