

**K001133 VITRO CHEMISTRY PRODUCTS ECO2 SLIDE &
CALIBRATOR KIT 2**Apr 24, 2000
14 days to decisionK001133 · Product code: **KHS** · Chemistry
Source: <https://www.510kdatabase.net/k001133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzymatic, Carbon-dioxide (KHS)
Date received	Apr 10, 2000
Decision date	Apr 24, 2000
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001133/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026