

K120765 VITROS CHEMISTRY PRODUCTS ECO2 SLIDESOct 24, 2012
225 days to decisionK120765 · Product code: **KHS** · Chemistry
Source: <https://www.510kdatabase.net/k120765/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Enzymatic, Carbon-dioxide (KHS) |
| Date received | Mar 13, 2012 |
| Decision date | Oct 24, 2012 |
| Days to decision | 225 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120765/> 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 15, 2026