

**K042520 VITROS CHEMISTRY PRODUCTS CAFFN REAGENT
KIT AND TDM PERFORMANCE VERIFIERS I, II AND III**Nov 30, 2004
75 days to decisionK042520 · Product code: **KLS** · Toxicology
Source: <https://www.510kdatabase.net/k042520/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Theophylline (KLS) |
| Date received | Sep 16, 2004 |
| Decision date | Nov 30, 2004 |
| Days to decision | 75 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042520/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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