

**K041799 VITROS CHEMISTRY PRODUCTS HSCR P REAGENT,
VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 17, VITROS
CHEMISTRY PRODUCTS FS**Aug 25, 2004
54 days to decisionK041799 · Product code: **NQD** · Chemistry
Source: <https://www.510kdatabase.net/k041799/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cardiac C-reactive Protein, Antigen, Antiserum, And Control (NQD) |
| Date received | Jul 2, 2004 |
| Decision date | Aug 25, 2004 |
| Days to decision | 54 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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