

**K042494 VITROS CHEMISTRY PRODUCTS C3 AND CR
REAGENT, CALIBRATOR KIT 20, PROTEIN PERFORMANCE
VERIFIERS I, II, AND III**Oct 19, 2004
35 days to decisionK042494 · Product code: **CZW** · Immunology
Source: <https://www.510kdatabase.net/k042494/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Complement C3, Antigen, Antiserum, Control (CZW) |
| Date received | Sep 14, 2004 |
| Decision date | Oct 19, 2004 |
| Days to decision | 35 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ortho-Clinical Diagnostics |
| Location | Rochester, NY, US |
| Contact | Darlene J Phillips |
| 510(k) history | 38 submissions · 38 cleared · 1999-2024 |

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunohematology. Now part of QuidelOrtho, the brand operates with global research and development centered in Rochester, New York. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Recent clearances span chemistry devices, immunology assays, and microbiology reagents, reflecting the company's focus on diagnostic platforms and assays for disease detection and blood compatibility testing. The V...

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