

**K063143 VITROS IMMUNODIAGNOSTIC PRODUCTS RUBELLA
IGG REAGANT PACK AND CALIBRATORS**Dec 26, 2006
71 days to decisionK063143 · Product code: LFX · Microbiology
Source: <https://www.510kdatabase.net/k063143/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Rubella (LFX) |
| Date received | Oct 16, 2006 |
| Decision date | Dec 26, 2006 |
| Days to decision | 71 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063143/> 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