

K993291 COPALIS RUBELLA IGMFeb 10, 2000
132 days to decisionK993291 · Product code: **LFX** · Microbiology
Source: <https://www.510kdatabase.net/k993291/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Rubella (LFX) |
| Date received | Oct 1, 1999 |
| Decision date | Feb 10, 2000 |
| Days to decision | 132 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | DiaSorin, Inc. |
| Location | Ellicott City, MD, US |
| Contact | JUDITH J SMITH |
| 510(k) history | 71 submissions · 70 cleared · 1998-2026 |

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