

K881243 RUBELLA IGG - EIA TEST KIT NUMBER 61 07 201Apr 4, 1988
14 days to decisionK881243 · Product code: LFX · Microbiology
Source: <https://www.510kdatabase.net/k881243/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Rubella (LFX) |
| Date received | Mar 21, 1988 |
| Decision date | Apr 4, 1988 |
| Days to decision | 14 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Labsystems, Inc. |
| Location | Walker, MI, US |
| Contact | NANCY SKOWRONSKI |
| 510(k) history | 17 submissions · 17 cleared · 1984-1993 |

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