

**K852788 RUBALEX**Mar 12, 1986  
254 days to decisionK852788 · Product code: **LQN** · Microbiology  
Source: <https://www.510kdatabase.net/k852788/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Latex Agglutination Assay, Rubella (LQN) |
| Date received         | Jul 1, 1985                              |
| Decision date         | Mar 12, 1986                             |
| Days to decision      | 254 days                                 |
| Third-party review    | No                                       |

**APPLICANT**

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|----------------|---|
| Company        | <b>Orion Corp.</b>                      |
| Location       | 20101 Turku, FL                         |
| Contact        | TIMO RAINES                             |
| 510(k) history | 21 submissions · 20 cleared · 1985-1992 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852788/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 21, 2026