

**K950900 OLYMPUS IGM IMMUNOTURBIDIMETRIC REAGENT**Mar 27, 1995  
27 days to decisionK950900 · Product code: **CFQ** · Immunology  
Source: <https://www.510kdatabase.net/k950900/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Radioimmunoassay, Immunoglobulins (g, A, M) (CFQ) |
| Date received         | Feb 28, 1995                                      |
| Decision date         | Mar 27, 1995                                      |
| Days to decision      | 27 days   |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Olympus America, Inc.</b>              |
| Location       | Lake Success, NY, US                      |
| Contact        | LAURA STORMS-TYLER                        |
| 510(k) history | 149 submissions · 149 cleared · 1994-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950900/> 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 18, 2026