

**K951055 OLYMPUS IGA IMMUNOTURBIDIMETRIC REAGENT**Apr 17, 1995  
41 days to decisionK951055 · Product code: **CFQ** · Immunology  
Source: <https://www.510kdatabase.net/k951055/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Immunoglobulins (g, A, M) (CFQ)
Date received	Mar 7, 1995
Decision date	Apr 17, 1995
Days to decision	41 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951055/> 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