

**K073490 OLYMPUS IGG REAGENT**Feb 11, 2008  
61 days to decisionK073490 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k073490/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Dec 12, 2007
Decision date	Feb 11, 2008
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus America, Inc.</b>
Location	Lake Success, NY, US
Contact	STEPHANIE G DONNELLY
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/k073490/> 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