

K073489 OLYMPUS IGA REAGENTFeb 11, 2008
61 days to decisionK073489 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k073489/>**SUBMISSION DETAILS**

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

Company	Olympus America, Inc.
Location	Lake Success, NY, US
Contact	STEPHANIE G DONNELLY
510(k) history	149 submissions · 149 cleared · 1994-2012

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