

**K083445 N ANTISERA TO HUMAN IMMUNOGLOBULINS (IGG, IGA AND IGM) AND N/T PROTEIN CONTROL LC**

Mar 24, 2009  
123 days to decision

K083445 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k083445/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Nov 21, 2008
Decision date	Mar 24, 2009
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics</b>
Location	Newark, DE, US
Contact	HELEN M LEE
510(k) history	92 submissions · 92 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k083445/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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