

K233663 N Antisera to Human Immunoglobulins (IgG, IgA, and IgM)Dec 13, 2023
28 days to decisionK233663 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k233663/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Nov 15, 2023
Decision date	Dec 13, 2023
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics Products GmbH
Location	Marburg, DE
Contact	Sanja Matern
510(k) history	19 submissions · 18 cleared · 2016-2024

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