

K191985 Optilite IgA KitAug 19, 2019
25 days to decisionK191985 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k191985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Jul 25, 2019
Decision date	Aug 19, 2019
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	The Binding Site Group , Ltd.
Location	Los Angeles, CA, US
Contact	Natasha Verhaak
Website	http://www.bindingsite.com/
510(k) history	43 submissions · 43 cleared · 2010-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191985/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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