

K191635 Optilite IgM Kit

Jul 15, 2019
26 days to decision

K191635 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k191635/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Jun 19, 2019
Decision date	Jul 15, 2019
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	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.net

Device record: <https://www.510kdatabase.net/k191635/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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