FDA 510(k) Premarket Notification

K150526 Optilite IgG4 Kit

CLEARED

May 30, 2015
89 days to decision

K150526 · Product code: **CFN** · Immunology
Source: https://www.510kdatabase.net/k150526/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Mar 2, 2015
Decision date	May 30, 2015
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**The Binding Site Group , Ltd.**
Location	Los Angeles, CA, US
Contact	Andrea Thomas
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/k150526/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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