

K192116 Human IgA liquid reagent kit for Use on SPAPlus

Sep 4, 2019
29 days to decision

K192116 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k192116/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Aug 6, 2019
Decision date	Sep 4, 2019
Days to decision	29 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/k192116/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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