

**K191465 Human IgM Kit for use on SPAPLus**Jun 27, 2019  
24 days to decisionK191465 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k191465/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Jun 3, 2019
Decision date	Jun 27, 2019
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191465/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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