

**K183151 Outilite IgA CSF Kit**Jan 23, 2019  
70 days to decisionK183151 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k183151/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Nov 14, 2018
Decision date	Jan 23, 2019
Days to decision	70 days
Third-party review	No
Combination product	No
PCCP authorized	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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