

**K190686 Optilite IgM CSF Kit**May 28, 2019  
71 days to decisionK190686 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k190686/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Mar 18, 2019
Decision date	May 28, 2019
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190686/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 1, 2026