

**K161982 C-Reactive Protein Kit for use on SPAPLUS**Apr 5, 2017  
260 days to decisionK161982 · Product code: **DCN** · Immunology  
Source: <https://www.510kdatabase.net/k161982/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, C-reactive Protein (DCN)
Date received	Jul 19, 2016
Decision date	Apr 5, 2017
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>The Binding Site Group</b>
Location	Birmingham, GB
Contact	KIRSTY SAMUELS
Website	<a href="http://www.bindingsite.com/">http://www.bindingsite.com/</a>
510(k) history	1 submissions · 1 cleared · 2017-2017

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161982/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026