

**K152433 VITROS Chemistry Products CRP Slides**Sep 24, 2015  
28 days to decisionK152433 · Product code: **DCK** · Immunology  
Source: <https://www.510kdatabase.net/k152433/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Aug 27, 2015
Decision date	Sep 24, 2015
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary
Other names	VITRO Chemistry Products Calibrator Kit 7

**APPLICANT**

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Company	<b>Ortho-Clinical Diagnostics</b>
Location	Rochester, NY, US
Contact	Jessica Miller
510(k) history	38 submissions · 38 cleared · 1999-2024

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunohematology. Now part of QuidelOrtho, the brand operates with global research and development centered in Rochester, New York. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Recent clearances span chemistry devices, immunology assays, and microbiology reagents, reflecting the company's focus on diagnostic platforms and assays for disease detection and blood compatibility testing. The V...

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