

**K142993 QuikRead go CRP, QuikRead go CRP Verification Set,
QuikRead go CRP Control Set, and QuikRead go Instrument**Mar 10, 2016
511 days to decisionK142993 · Product code: **DCK** · Immunology
Source: <https://www.510kdatabase.net/k142993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Oct 16, 2014
Decision date	Mar 10, 2016
Days to decision	511 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Orion Diagnostica, OY
Location	Espoo, FI
Contact	ANJA KONTIO
510(k) history	4 submissions · 4 cleared · 2004-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142993/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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