

K141689 FastPack High Sensitivity C-Reactive Protein Immunoassay, High Sensitivity C-Reactive Protein Calibrator Kit, FastPack High Sensitivity C-Reactive Protein Controls, FastPack High Sensitivity C-Reactive Protein Method Verification KitJan 7, 2015
198 days to decisionK141689 · Product code: **DCK** · Chemistry
Source: <https://www.510kdatabase.net/k141689/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Jun 23, 2014
Decision date	Jan 7, 2015
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Qualigen, Inc.
Location	Carlsbad, CA, US
Contact	Michael Poirier
510(k) history	15 submissions · 15 cleared · 2000-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141689/> Data sourced from FDA 510(k) public records (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. - Generated June 19, 2026