

**K113809 HITACHI CLINICAL ANALYZER S TEST REAGENT  
CARTRIDGE C-REACTIVE PROTEIN (CRP)**Aug 17, 2012  
238 days to decisionK113809 · Product code: **DCN** · Immunology  
Source: <https://www.510kdatabase.net/k113809/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, C-reactive Protein (DCN)
Date received	Dec 23, 2011
Decision date	Aug 17, 2012
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hitachi Chemical Diagnostics, Inc.</b>
Location	Mountain View, CA, US
Contact	ERICKA B AMMIRATI
510(k) history	16 submissions · 16 cleared · 2003-2021

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113809/> 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 May 26, 2026