

K003400 CRP HS TEST SYSTEMMay 10, 2001
190 days to decisionK003400 · Product code: **DCN** · Immunology
Source: <https://www.510kdatabase.net/k003400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, C-reactive Protein (DCN)
Date received	Nov 1, 2000
Decision date	May 10, 2001
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	KAY A TAYLOR
510(k) history	264 submissions · 263 cleared · 1999-2013

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