

K982087 ROCHE CRP T CONTROL NAug 18, 1998
64 days to decisionK982087 · Product code: **DCK** · Immunology
Source: <https://www.510kdatabase.net/k982087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Jun 15, 1998
Decision date	Aug 18, 1998
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	RITA SMITH
510(k) history	296 submissions · 296 cleared · 1983-1999

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