

K011958 CRP-LATEX (II) SEIKEN HIGH SENSITIVITY ASSAY KITDec 4, 2001
165 days to decisionK011958 · Product code: **DCN** · Chemistry
Source: <https://www.510kdatabase.net/k011958/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, C-reactive Protein (DCN)
Date received	Jun 22, 2001
Decision date	Dec 4, 2001
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Denka Seiken&apos;S
Location	Tokyo, JP
Contact	SEIYA SATO
510(k) history	4 submissions · 4 cleared · 1998-2002

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