

**K030545 CRP-LATEX (II)X2 SEIKEN ASSAY KIT**Jun 2, 2003  
102 days to decisionK030545 · Product code: **DCK** · Immunology  
Source: <https://www.510kdatabase.net/k030545/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Feb 20, 2003
Decision date	Jun 2, 2003
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Denka Seiken Co., Ltd.</b>
Location	Gosen City, Niigata, JP
Contact	TOSHIMI MATSUNAGA
510(k) history	6 submissions · 6 cleared · 2003-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030545/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026