

**K013359 LP(A)-LATEX SEIKEN ASSAY KIT**Mar 8, 2002  
149 days to decisionK013359 · Product code: **DFC** · Chemistry  
Source: <https://www.510kdatabase.net/k013359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Oct 10, 2001
Decision date	Mar 8, 2002
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Denka Seiken&amp;apos;S</b>
Location	Tokyo, JP
Contact	YOUSUKE MEGURO
510(k) history	4 submissions · 4 cleared · 1998-2002

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