

K043264 LDL-EX SEIKEN ASSAY KITJan 26, 2005
63 days to decisionK043264 · Product code: **MRR** · Chemistry
Source: <https://www.510kdatabase.net/k043264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Low Density, Lipoprotein (MRR)
Date received	Nov 24, 2004
Decision date	Jan 26, 2005
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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