

**K041090 HDL-EX SEIKEN ASSAY KIT**Oct 29, 2004  
186 days to decisionK041090 · Product code: **LBS** · Chemistry  
Source: <https://www.510kdatabase.net/k041090/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Apr 26, 2004
Decision date	Oct 29, 2004
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041090/> 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