

K990581 DIRECT HDL-CHOLESTEROL REAGENTJun 18, 1999
115 days to decisionK990581 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k990581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Feb 23, 1999
Decision date	Jun 18, 1999
Days to decision	115 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kamiya Biomedical Co.
Location	Thousand Oaks, CA, US
Contact	COLIN GETTY
510(k) history	43 submissions · 43 cleared · 1991-2010

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