

**K041928 HDL-ADVANCE ASSAY, CAT. NO. 278-20, 278-50A,
278-50B**Nov 23, 2004
127 days to decisionK041928 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k041928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Jul 19, 2004
Decision date	Nov 23, 2004
Days to decision	127 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diagnostic Chemicals , Ltd.
Location	Charlottetown, P.E.I., CA
Contact	NANCY OLSCAMP
510(k) history	66 submissions · 66 cleared · 1994-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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