

**K072395 DIAZYME HDL-CHOLESTEROL
REAGENT,CALIBRATOR, CONTROLS**Jan 3, 2008
129 days to decisionK072395 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k072395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Aug 27, 2007
Decision date	Jan 3, 2008
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diazyme Laboratories
Location	Irvine, CA, US
Contact	CHARLES YU
510(k) history	41 submissions · 41 cleared · 2003-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072395/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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