

**K992029 ATAC DIRECT HDL CHOLESTEROL REAGENT AND
ATAC HDL-C CALIBRATOR KITS**Aug 12, 1999
57 days to decisionK992029 · Product code: **LBR** · Chemistry
Source: <https://www.510kdatabase.net/k992029/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Hdl (LBR)
Date received	Jun 16, 1999
Decision date	Aug 12, 1999
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Elan Diagnostics
Location	Brea, CA, US
Contact	WYNN STOCKING
510(k) history	13 submissions · 13 cleared · 1999-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992029/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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