

K071706 ENVOY 500 HDLDec 20, 2007
182 days to decisionK071706 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k071706/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Jun 21, 2007
Decision date	Dec 20, 2007
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary
Other names	CHOLESTEROL REAGENT KIT (MODEL# 55301), CALIBRATOR KIT (MODEL# 55118)

APPLICANT

Company	Clinical Data, Inc.
Location	Mchenry, IL, US
Contact	WYNN STOCKING
510(k) history	36 submissions · 36 cleared · 1982-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071706/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026