

K100550 POLY-CHEM 90 DIRECT HDL CHOLESTEROL, POLY-CHEM 90 DIRECT LDL CHOLESTEROL, POLY-CHEM 90 CHOLESTEROL, POLY-CHEM 90 TRIGLYCSep 28, 2010
214 days to decisionK100550 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k100550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Feb 26, 2010
Decision date	Sep 28, 2010
Days to decision	214 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Polymedco, Inc.
Location	Cortlandt Manor, NY, US
Contact	HELEN LANDICHO
510(k) history	19 submissions · 19 cleared · 1992-2011

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