

**K891117 HDL CHOLESTEROL REAGENT**Apr 10, 1989  
39 days to decisionK891117 · Product code: **LBR** · Chemistry  
Source: <https://www.510kdatabase.net/k891117/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Hdl (LBR)
Date received	Mar 2, 1989
Decision date	Apr 10, 1989
Days to decision	39 days
Third-party review	No

**APPLICANT**

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Company	<b>Pointe Scientific, Inc.,</b>
Location	Mchenry, IL, US
Contact	WILLIAM F WALTERS
510(k) history	74 submissions · 74 cleared · 1981-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k891117/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 26, 2026