

**K895381 HDL SINGLES**Nov 8, 1989  
71 days to decisionK895381 · Product code: **LBR** · Chemistry  
Source: <https://www.510kdatabase.net/k895381/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Hdl (LBR)
Date received	Aug 29, 1989
Decision date	Nov 8, 1989
Days to decision	71 days
Third-party review	No

**APPLICANT**

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Company	<b>Trace America, Inc.</b>
Location	Miami, FL, US
Contact	David Johnston
510(k) history	22 submissions · 22 cleared · 1988-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895381/>, 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 30, 2026