

**K972041 EZ HDL CHOLESTEROL REAGENT(PROCEDURE  
354)/EZ HDL CALIBRATOR (354-5)**Jul 22, 1997  
50 days to decisionK972041 · Product code: **LBS** · Chemistry  
Source: <https://www.510kdatabase.net/k972041/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Jun 2, 1997
Decision date	Jul 22, 1997
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972041/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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