

**K053157 AUTOMATED HDL CHOLESTEROL FLEX REAGENT  
CARTRIDGE, MODEL DF48A**Dec 9, 2005  
25 days to decisionK053157 · Product code: **LBS** · Chemistry  
Source: <https://www.510kdatabase.net/k053157/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Nov 14, 2005
Decision date	Dec 9, 2005
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dade Behring, Inc.</b>
Location	Newark,, DE, US
Contact	VICTOR M CARRIO
510(k) history	343 submissions · 343 cleared · 1978-2010

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053157/> 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 19, 2026