

**K013152 ATAC PAK DIRECT HDL REAGENT AND ATAC  
DIRECT HDL CALIBRATOR KITS**Nov 9, 2001  
50 days to decisionK013152 · Product code: **LBS** · Chemistry  
Source: <https://www.510kdatabase.net/k013152/>**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	Sep 20, 2001
Decision date	Nov 9, 2001
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elan Holdings, Inc.</b>
Location	Brea, CA, US
Contact	WYNN STOCKING
510(k) history	12 submissions · 12 cleared · 1999-2001

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