

**K151809 Alere Afinion HbA1c, Alere Afinion AS100 Analyzer**Sep 25, 2015  
85 days to decisionK151809 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k151809/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jul 2, 2015
Decision date	Sep 25, 2015
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alere Technologies AS</b>
Location	Oslo, NO
Contact	Kari Skinnemoen
510(k) history	3 submissions · 3 cleared · 2015-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151809/> 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 28, 2026