

K214117 Afinion™ HbA1c, Afinion™ 2 and Alere Afinion™ AS100 AnalyzerSep 27, 2023
636 days to decisionK214117 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k214117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Dec 30, 2021
Decision date	Sep 27, 2023
Days to decision	636 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Diagnostics Technologies AS
Location	Oslo, NO
Contact	Danial Kirmani
510(k) history	1 submissions · 1 cleared · 2023-2023

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