

K171650 Alere Afinion HbA1c and ACR on Afinion 2 analyzerNov 21, 2017
169 days to decisionK171650 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k171650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 5, 2017
Decision date	Nov 21, 2017
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Rapid Diagnostics
Location	San Deigo, CA, US
Contact	Monica Vallestad
510(k) history	1 submissions · 1 cleared · 2017-2017

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