

K182988 Afinion HbA1c Dx on Afinion 2Nov 29, 2018
31 days to decisionK182988 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k182988/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Oct 29, 2018
Decision date	Nov 29, 2018
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alere Technologies AS
Location	Oslo, NO
Contact	Monica Vallestad
510(k) history	3 submissions · 3 cleared · 2015-2018

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