

K180296 Afinion HbA1c DxMay 7, 2018
94 days to decisionK180296 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k180296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Feb 2, 2018
Decision date	May 7, 2018
Days to decision	94 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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