

K182651 HbA1c AdvancedJan 16, 2019
114 days to decisionK182651 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k182651/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Sep 24, 2018
Decision date	Jan 16, 2019
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter Ireland, Inc.
Location	Brea, CA, US
Contact	Catriona Hourigan
510(k) history	7 submissions · 7 cleared · 2013-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182651/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026