

K162822 ADAMS A1c HA-8180V, CALIBRATOR 80Jun 29, 2017
265 days to decisionK162822 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k162822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Oct 7, 2016
Decision date	Jun 29, 2017
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arkray Factory, Inc.
Location	Edina, MN, US
Contact	Kazuya Yorimitsu
510(k) history	6 submissions · 6 cleared · 2014-2019

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