

K173206 SEKURE HbA1c AssayJul 12, 2018
283 days to decisionK173206 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k173206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Oct 2, 2017
Decision date	Jul 12, 2018
Days to decision	283 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sekisui Diagnostics P.E.I., Inc.
Location	Prince Edward Island, CA
Contact	Penny White
510(k) history	6 submissions · 6 cleared · 2011-2022

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