

K183230 OneDraw A1C Test SystemAug 15, 2019
268 days to decisionK183230 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k183230/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Nov 20, 2018
Decision date	Aug 15, 2019
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Drawbridge Health, Inc.
Location	San Diego, CA, US
Contact	Annie Wright
510(k) history	2 submissions · 2 cleared · 2019-2024

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