

K192987 Aina HbA1c Monitoring System 2Mar 26, 2020
153 days to decisionK192987 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k192987/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Oct 25, 2019
Decision date	Mar 26, 2020
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jana Care, Inc.
Location	Boston, MA, US
Contact	Michal Depa
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	MDC Associates, Inc.
Contact	Fran White

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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