

**K140827 SD A1cCare System, SD A1cCare Spoit Type Test Kit,
SD HbA1c Control Set**Sep 30, 2015
547 days to decisionK140827 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k140827/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Apr 1, 2014
Decision date	Sep 30, 2015
Days to decision	547 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sd Biosensor, Inc.
Location	Mission Viejo, CA, US
Contact	Yeon Park
510(k) history	2 submissions · 2 cleared · 2015-2015

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