

**K173127 skyla Hi Hemoglobin A1c System (skyla Hi Analyzer and skyla Hi Hemoglobin A 1 c Reagent Kit)**Sep 25, 2018  
361 days to decisionK173127 · Product code: LCP · Chemistry  
Source: <https://www.510kdatabase.net/k173127/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Sep 29, 2017
Decision date	Sep 25, 2018
Days to decision	361 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Skyla Corporation H.S.P.B</b>
Location	Hsinchu City, TW
Contact	Cindy Lu
510(k) history	1 submissions · 1 cleared · 2018-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Ivdd Regulatory Consultant</b>
Contact	Feng-Yu Lee

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173127/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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