

K192369 PixoTest POCT System - PixoTest POCT Analyzer and PixoTest A1c Test KitOct 29, 2019
60 days to decisionK192369 · Product code: LCP · Chemistry
Source: <https://www.510kdatabase.net/k192369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Aug 30, 2019
Decision date	Oct 29, 2019
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ixensor Co, Ltd.
Location	Taipei City, TW
Contact	Evita Chen
510(k) history	2 submissions · 2 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Ivdd Regulatory Consultant
Contact	Feng-Yu Lee

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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