

K181915 PixoTest POCT System - PixoTest POCT Analyzer and PixoTest A1c Test KitApr 12, 2019
269 days to decisionK181915 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k181915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jul 17, 2018
Decision date	Apr 12, 2019
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ixensor Co, Ltd.
Location	Taipei City, TW
Contact	Ariel Huang
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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181915/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026