

K231465 Q-Pad Test SystemDec 6, 2023
201 days to decisionK231465 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k231465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 19, 2023
Decision date	Dec 6, 2023
Days to decision	201 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qurasense
Location	Menlo Park, CA, US
Contact	Sara Naseri
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Hyman, Phelps & McNamara, P.C.
Contact	Richard A. Lewis

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT04243239**

[Trial of device that is not approved or cleared by the U.S. FDA]

Status	Withheld - <i>No results published to ClinicalTrials.gov</i>
Sponsor	[Redacted]

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04243239510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231465/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), [ClinicalTrials.gov](https://clinicaltrials.gov) (U.S. National Library of Medicine).
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