

K223179 Cholestech LDX™ SystemSep 20, 2023
344 days to decisionK223179 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k223179/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Oct 11, 2022
Decision date	Sep 20, 2023
Days to decision	344 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alere San Diego, Inc.
Location	San Diego, CA, US
Contact	Nathifa Bradshaw
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223179/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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