

K163433 VITROS Chemistry Products GLU SlidesSep 18, 2017
285 days to decisionK163433 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k163433/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Dec 7, 2016
Decision date	Sep 18, 2017
Days to decision	285 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	Darlene J. Phillips
510(k) history	38 submissions · 38 cleared · 1999-2024

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunochemistry. Now part of QuidelOrtho, the brand operates with global research and development centered in Rochester, New York. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Recent clearances span chemistry devices, immunology assays, and microbiology reagents, reflecting the company's focus on diagnostic platforms and assays for disease detection and blood compatibility testing. The V...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163433/> 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 May 13, 2026