

K190520 VITROS XT Chemistry Products GLU-Ca SlidesApr 3, 2019
30 days to decisionK190520 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k190520/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Mar 4, 2019
Decision date	Apr 3, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	Darlene Phillips
510(k) history	106 submissions · 104 cleared · 1997-2025

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