

**K162020 VITROS Chemistry Products CI- Slides**Dec 16, 2016  
148 days to decisionK162020 · Product code: **CGZ** · Chemistry  
Source: <https://www.510kdatabase.net/k162020/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion-specific, Chloride (CGZ)
Date received	Jul 21, 2016
Decision date	Dec 16, 2016
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortho-Clinical Diagnostics</b>
Location	Rochester, NY, US
Contact	Marlene Hanna
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k162020/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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