

**K142595 VITROS Chemistry Products HbA 1c Reagent Kit,
VITROS Calibrator Kit 31, VITROS Chemistry Products %A1c
Performance Verifiers I and II**Jun 4, 2015
262 days to decisionK142595 · Product code: **PDJ** · Chemistry
Source: <https://www.510kdatabase.net/k142595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemoglobin A1c Test System (PDJ)
Date received	Sep 15, 2014
Decision date	Jun 4, 2015
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	Bradley P Boyer
510(k) history	38 submissions · 38 cleared · 1999-2024

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunohematology. 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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