

K031924 VITROS 5,1 FS CHEMISTRY SYSTEM, VITROS CHEMISTRY PRODUCTS DHDL REAGENT PACK, CALIBRATOR KIT 19, FS CALIBRATOR 1Aug 7, 2003
45 days to decisionK031924 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k031924/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Jun 23, 2003
Decision date	Aug 7, 2003
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	NEIL GREENBERG
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...