

**K101921 VITROS IMMUNODIAGNOSTICS PRODUCTS INTACT
PTH REAGENT PACK, VITROS IMMUNODIAGNOSTICS
PRODUCTS INTACT PTH CALIBRATORS, VIT**Oct 22, 2010
105 days to decisionK101921 · Product code: **CEW** · Chemistry
Source: <https://www.510kdatabase.net/k101921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Jul 9, 2010
Decision date	Oct 22, 2010
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	DECLAN HYNES
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...