

K060480 VITROS IMMUNODIAGNOSTIC PRODUCTS CORTISOL REAGENT PACK AND CALIBRATORS AND METABOLISM CONTROLSJul 3, 2006
130 days to decisionK060480 · Product code: **CGR** · Chemistry
Source: <https://www.510kdatabase.net/k060480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Cortisol (CGR)
Date received	Feb 23, 2006
Decision date	Jul 3, 2006
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	LEAH VAN DE WATER
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...