

K001769 VITROS CHEMISTRY PRODUCTS CREA DT SLIDESJun 21, 2000
9 days to decisionK001769 · Product code: **CGX** · Chemistry
Source: <https://www.510kdatabase.net/k001769/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	Jun 12, 2000
Decision date	Jun 21, 2000
Days to decision	9 days
Third-party review	No
Summary / Statement	Summary
Other names	VITROS CHEMISTRY PRODUCTS DT CALIBRATOR KIT

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	Darlene J Phillips
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...
