

K062165 VITROS CHEMISTRY PRODUCTS BARB REAGENTJan 5, 2007
161 days to decisionK062165 · Product code: **DIS** · Chemistry
Source: <https://www.510kdatabase.net/k062165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Jul 28, 2006
Decision date	Jan 5, 2007
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary
Other names	CALIBRATOR KIT 26; FS CALIBRATOR 1; DAT PERFORMANCE VERIFIERS

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	MARLENE HANNA
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...
