

**K052645 VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT
28, REF 680 2323**Dec 14, 2005
79 days to decisionK052645 · Product code: **GTQ** · Microbiology
Source: <https://www.510kdatabase.net/k052645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antistreptolysin - Titer/streptolysin O Reagent (GTQ)
Date received	Sep 26, 2005
Decision date	Dec 14, 2005
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary
Other names	VITROS CHEMISTRY PRODUCTS FS CALIBRATOR 1, REF 6801873;

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	MICHAEL M BYRNE
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...

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Device record: <https://www.510kdatabase.net/k052645/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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