

K042477 VITROS CHEMISTRY PRODUCTS TRFRN REAHENTNov 19, 2004
67 days to decisionK042477 · Product code: **DDG** · Chemistry
Source: <https://www.510kdatabase.net/k042477/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transferrin, Antigen, Antiserum, Control (DDG)
Date received	Sep 13, 2004
Decision date	Nov 19, 2004
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary
Other names	VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 20; VITROS CHEMISTRY PRODUCTS PROTEIN

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	Darlene J Phillips
510(k) history	106 submissions · 104 cleared · 1997-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042477/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026