

**K982649 VITROS CHEMISTRY PRODUCTS TDM  
PERFORMANCE VERIFIERS I, II, AND III**Aug 12, 1998  
13 days to decisionK982649 · Product code: **DIF** · Chemistry  
Source: <https://www.510kdatabase.net/k982649/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Mixture Control Materials (DIF)
Date received	Jul 30, 1998
Decision date	Aug 12, 1998
Days to decision	13 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ortho-Clinical Diagnostics, Inc.</b>
Location	Rochester, NY, US
Contact	CHARLES C MORGANSON, JR.
510(k) history	106 submissions · 104 cleared · 1997-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982649/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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