

K984288 VITROS CHEMISTRY PRODUCTS PHBR SLIDESJan 26, 1999
56 days to decisionK984288 · Product code: **DLZ** · Toxicology
Source: <https://www.510kdatabase.net/k984288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phenobarbital (DLZ)
Date received	Dec 1, 1998
Decision date	Jan 26, 1999
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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