

**K210858 VITROS Chemistry Products PHBR Slides**Aug 13, 2021  
143 days to decisionK210858 · Product code: **DLZ** · Toxicology  
Source: <https://www.510kdatabase.net/k210858/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phenobarbital (DLZ)
Date received	Mar 23, 2021
Decision date	Aug 13, 2021
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortho-Clinical Diagnostics, Inc.</b>
Location	Rochester, NY, US
Contact	Darlene Phillips
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/k210858/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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