

K130332 VITROS CHEMISTRY PRODUCTS TRIG SLIDESMay 31, 2013
109 days to decisionK130332 · Product code: **CDT** · Chemistry
Source: <https://www.510kdatabase.net/k130332/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lipase Hydrolysis/glycerol Kinase Enzyme, Triglycerides (CDT)
Date received	Feb 11, 2013
Decision date	May 31, 2013
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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