

**K043384 VITROS CHEMISTRY PRODUCTS TOBRA REAGENT,
CALBRATOR KIT 14 AND TDM PERFORMANCE VERIFIERS I, II
AND III**Feb 7, 2005
60 days to decisionK043384 · Product code: **LDO** · Chemistry
Source: <https://www.510kdatabase.net/k043384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Radiochemical Assay, Tobramycin (LDO)
Date received	Dec 9, 2004
Decision date	Feb 7, 2005
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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