

K042479 VITROS CHEMISTRY PRODUCTS GENT, TOBRA & VANC REAGENTSJan 6, 2005
115 days to decisionK042479 · Product code: **LCD** · Toxicology
Source: <https://www.510kdatabase.net/k042479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Gentamicin (LCD)
Date received	Sep 13, 2004
Decision date	Jan 6, 2005
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary
Other names	VITROS CHEMISTYR PRODUCTS CALIBRATOR KITS 11, 13 & 14; VITROS CHE

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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