

K160495 VITROS® Automation SolutionsOct 18, 2016
239 days to decisionK160495 · Product code: **KLI** · Chemistry
Source: <https://www.510kdatabase.net/k160495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Feb 22, 2016
Decision date	Oct 18, 2016
Days to decision	239 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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