

**K081543 VITROS IMMUNODIAGNOSTIC PRODUCTS TSH
REAGENT PACK AND CALIBRATORS, VITROS 5600
INTEGRATED SYSTEM**Oct 23, 2008
143 days to decisionK081543 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k081543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Jun 2, 2008
Decision date	Oct 23, 2008
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081543/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026