

**K083173 VITROS IMMUNODIAGNOSTIC PRODUCTS TSH
REAGENT PACK AND CALIBRATORS, VITROS 3600
IMMUNODIAGNOSTIC SYSTEM**Dec 22, 2008
56 days to decisionK083173 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k083173/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Oct 27, 2008
Decision date	Dec 22, 2008
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	LEAH VAN DE WATER
510(k) history	38 submissions · 38 cleared · 1999-2024

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunochemistry. Now part of QuidelOrtho, the brand operates with global research and development centered in Rochester, New York. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Recent clearances span chemistry devices, immunology assays, and microbiology reagents, reflecting the company's focus on diagnostic platforms and assays for disease detection and blood compatibility testing. The V...