

K994145 VITROS IMMUNODIAGNOSTIC PRODUCTS FREE T3 REAGENT PACK, VITROS IMMUNODIAGNOSTIC PRODUCTS FREE T3 CALIBRATORSDec 22, 1999
14 days to decisionK994145 · Product code: **JIS** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Primary (JIS)
Date received	Dec 8, 1999
Decision date	Dec 22, 1999
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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