

**K992366 VITROS IMMUNODIAGNOSTIC PRODUCTS TROPONIN
I REAGENT PACK**Oct 8, 1999
85 days to decisionK992366 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k992366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jul 15, 1999
Decision date	Oct 8, 1999
Days to decision	85 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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