

**K031031 VITROS IMMUNODIAGNOSTIC PRODUCTS TROPONIN
I REAGENT PACK AND CALIBRATORS**Sep 29, 2003
181 days to decisionK031031 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k031031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Apr 1, 2003
Decision date	Sep 29, 2003
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031031/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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