

**K020662 MODIFICATION TO VITROS IMMUNODIAGNOSTIC PRODUCTS TROPONIN I REAGENT PACK/ CALIBRATORS**Apr 12, 2002  
42 days to decisionK020662 · Product code: **MMI** · Chemistry  
Source: <https://www.510kdatabase.net/k020662/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Mar 1, 2002
Decision date	Apr 12, 2002
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortho-Clinical Diagnostics</b>
Location	Rochester, NY, US
Contact	ANN M QUINN
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...

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