

**K072732 ORTHO T. CRUZI ELISA TEST SYSTEM**Apr 15, 2009  
567 days to decisionK072732 · Product code: **MIU** · Microbiology  
Source: <https://www.510kdatabase.net/k072732/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, T. Cruzi (MIU)
Date received	Sep 26, 2007
Decision date	Apr 15, 2009
Days to decision	567 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortho-Clinical Diagnostics, Inc.</b>
Location	Rochester, NY, US
Contact	ANDREA J CASPER
510(k) history	106 submissions · 104 cleared · 1997-2025

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