

**K161947 Chagas Detect Plus Rapid Test**Dec 16, 2016  
155 days to decisionK161947 · Product code: **MIU** · Microbiology  
Source: <https://www.510kdatabase.net/k161947/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, T. Cruzi (MIU)
Date received	Jul 14, 2016
Decision date	Dec 16, 2016
Days to decision	155 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>InBios International, Inc.</b>
Location	Seattle, WA, US
Contact	ESTELA RAYCHAUDHURI
510(k) history	7 submissions · 5 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161947/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026