

**K100130 PATHFAST CTNI-II TEST, PATHFAST CTNI CALBRATORS, PATHFAST SAMPLE DILUENT 2**May 16, 2011  
482 days to decisionK100130 · Product code: **MMI** · Chemistry  
Source: <https://www.510kdatabase.net/k100130/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jan 19, 2010
Decision date	May 16, 2011
Days to decision	482 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mitsubishi Chemical Medience CO</b>
Location	Baldwin, MD, US
Contact	Judi Smith
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100130/> 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 June 19, 2026