

**K081360 PATHFAST CK-MB-II, PATHFAST MYO-II**Aug 17, 2009  
459 days to decisionK081360 · Product code: **JHX** · Chemistry  
Source: <https://www.510kdatabase.net/k081360/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorometric Method, Cpk Or Isoenzymes (JHX)
Date received	May 15, 2008
Decision date	Aug 17, 2009
Days to decision	459 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mitsubishi Kagaku Iatron</b>
Location	Seattle, WA, US
Contact	HELEN LANDICHO
510(k) history	4 submissions · 4 cleared · 2008-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081360/> 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 22, 2026