

**K051433 I-STAT CREATINE KINASE MB (CK-MB)**Dec 15, 2005  
197 days to decisionK051433 · Product code: **MYT** · Chemistry  
Source: <https://www.510kdatabase.net/k051433/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biosensor, Immunoassay, Cpk Or Isoenzymes (MYT)
Date received	Jun 1, 2005
Decision date	Dec 15, 2005
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>I-Stat Corporation</b>
Location	East Windsor, NJ, US
Contact	SUE KENT
510(k) history	7 submissions · 7 cleared · 2002-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051433/> 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 14, 2026