

**K082226 S40 CREATINE KINASE (CK)**Sep 18, 2008  
42 days to decisionK082226 · Product code: **JHS** · Chemistry  
Source: <https://www.510kdatabase.net/k082226/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Differential Rate Kinetic Method, Cpk Or Isoenzymes (JHS)
Date received	Aug 7, 2008
Decision date	Sep 18, 2008
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alfa Wassermann Diagnostic Technologies, Inc.</b>
Location	West Caldwell, NJ, US
Contact	DENNIS TASCHEK
510(k) history	21 submissions · 21 cleared · 2008-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082226/> 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 8, 2026