

**K080073 S-TEST CREATININE (CRE)**Jun 30, 2008  
171 days to decisionK080073 · Product code: **JFY** · Chemistry  
Source: <https://www.510kdatabase.net/k080073/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Jan 11, 2008
Decision date	Jun 30, 2008
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Alfa Wassermann, Inc.</b>
Location	West Caldwell, NJ, US
Contact	DAVID SLAVIN
510(k) history	5 submissions · 5 cleared · 2007-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080073/> 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