

**K092911 SMART HBA1C ASSAY KIT, MODEL DZ168B-POC,  
SMART HBA1C ASSAY CONTROL KIT, MODEL DZ168B-CON,  
SMART HBAC1C ANALYZER**Apr 26, 2010  
216 days to decisionK092911 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k092911/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 22, 2009
Decision date	Apr 26, 2010
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diazyme Laboratories</b>
Location	Irvine, CA, US
Contact	Abhijit Datta
510(k) history	41 submissions · 41 cleared · 2003-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092911/>; 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 31, 2026