

**K070734 MODIFICATION TO: DIRECT ENZYMATIC HBA1C  
ASSAY KIT, MODEL# DZ168A, DZ168A-CAL, DZ168A-CON**Apr 9, 2007  
24 days to decisionK070734 · Product code: LCP · Chemistry  
Source: <https://www.510kdatabase.net/k070734/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 16, 2007
Decision date	Apr 9, 2007
Days to decision	24 days
Third-party review	No
Summary / Statement	Statement

**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/k070734/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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