

**K110188 DIAZYME GLYCATED SERUM PROTEIN ASSAY /
CALBRATOR KIT / CONTROL KIT**May 17, 2011
113 days to decisionK110188 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k110188/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jan 24, 2011
Decision date	May 17, 2011
Days to decision	113 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110188/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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