

K133803 DIAZYME GLYCATED SERUM PROTEIN POC TEST KITAug 6, 2014
233 days to decisionK133803 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k133803/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Dec 16, 2013
Decision date	Aug 6, 2014
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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