

K160762 Diazyme Direct HbA1c Assay (Enzymatic, On-Board Lysis), Diazyme Direct HbA1c Assay Calibrator Set, Diazyme Direct HbA1c Assay Control Set

Nov 21, 2016
245 days to decision

K160762 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k160762/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 21, 2016
Decision date	Nov 21, 2016
Days to decision	245 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160762/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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