

**K131556 DIAZYME LIPOPROTEIN (A) CALIBRATOR SET,
CONTROL SET**

Jun 26, 2013
28 days to decision

K131556 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k131556/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Secondary (JIT)
Date received	May 29, 2013
Decision date	Jun 26, 2013
Days to decision	28 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/k131556/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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