FDA 510(k) Premarket Notification

CLEARED

K253069 Lipoprotein (a) Molarity Assay

Jun 16, 2026
266 days to decision

K253069 · Product code: **DFC** · Chemistry
Source: https://www.510kdatabase.net/k253069/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipoprotein, Low-density, Antigen, Antiserum, Control (DFC)
Date received	Sep 23, 2025
Decision date	Jun 16, 2026
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Diazyme Laboratories, Inc.**
Location	Poway, CA, US
Contact	Abhijit Datta
Website	https://www.diazyme.com/
510(k) history	11 submissions · 11 cleared · 2018-2026

Diazyme Laboratories, Inc. develops innovative clinical diagnostic reagents using proprietary enzyme and immunoassay technologies. Founded in 2000, the company specializes in diagnostic tests for cardiovascular disease, cancer, liver disease, renal disease, diabetes, sepsis, inflammatory disease, vitamins, and electrolytes. Diazyme operates a cGMP and ISO 13485 certified manufacturing facility in Poway, California, with additional operations in Europe and Shanghai. The company has received FDA 510(k) clearances from total submissions since 2018. Diazyme's cleared devices ...