

K203136 Diazyme PLAC® Test for Lp-PLA2 ActivityAug 6, 2021
290 days to decisionK203136 · Product code: **NOE** · Chemistry
Source: <https://www.510kdatabase.net/k203136/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, System, Immunoassay, Lipoprotein-associated Phospholipase A2 (NOE)
Date received	Oct 20, 2020
Decision date	Aug 6, 2021
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Diazyme Laboratories, Inc.
Location	Poway, CA, US
Contact	Chao Dou
Website	https://www.diazyme.com/
510(k) history	10 submissions · 10 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 ...

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