

K243462 Diazyme Colorimetric Lithium AssayAug 1, 2025
266 days to decisionK243462 · Product code: **NDW** · Chemistry
Source: <https://www.510kdatabase.net/k243462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Porphyrin, Spectrophotometry, Lithium (NDW)
Date received	Nov 8, 2024
Decision date	Aug 1, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Diazyme Laboratories, Inc.
Location	Poway, CA, US
Contact	Abhijit Datta
510(k) history	10 submissions · 10 cleared · 2018-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243462/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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