

**K252336 Diazyme Immunoglobulin A Assay**Apr 24, 2026  
270 days to decision

K252336 · Immunology

Source: <https://www.510kdatabase.net/k252336/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Jul 28, 2025
Decision date	Apr 24, 2026
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Diazyme Immunoglobulin G Assay; Diazyme Immunoglobulin M Assay

**APPLICANT**

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

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