

K253358 Diazyme Human Kappa (k) Free Light Chain AssayDec 19, 2025
80 days to decisionK253358 · Product code: **DFH** · Immunology
Source: <https://www.510kdatabase.net/k253358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Sep 30, 2025
Decision date	Dec 19, 2025
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Diazyme Human Lambda (λ) Free Light Chain Assay

APPLICANT

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

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