

K250408 Alegria Flash ENA ScreenSep 19, 2025
218 days to decisionK250408 · Product code: **LLL** · Immunology
Source: <https://www.510kdatabase.net/k250408/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Feb 13, 2025
Decision date	Sep 19, 2025
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Zeus Scientific
Location	Branchburg, NJ, US
Contact	Mark Koprinsky
510(k) history	5 submissions · 5 cleared · 2023-2025

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