

K250666 Alegria Flash CTD ScreenOct 22, 2025
231 days to decisionK250666 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k250666/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Mar 5, 2025
Decision date	Oct 22, 2025
Days to decision	231 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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