

K250814 Alegria Flash SSA-60May 8, 2026
417 days to decisionK250814 · Product code: **OBE** · Immunology
Source: <https://www.510kdatabase.net/k250814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-ss-a 52 Autoantibodies (OBE)
Date received	Mar 17, 2025
Decision date	May 8, 2026
Days to decision	417 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Alegria Flash SSA-52; Alegria FLash SSB

APPLICANT

Company	Zeus Scientific
Location	Branchburg, NJ, US
Contact	Daniel Zweitzig
510(k) history	6 submissions · 6 cleared · 2023-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250814/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 27, 2026