FDA 510(k) Premarket Notification

K251577 LAIA XR

CLEARED

Feb 6, 2026
260 days to decision

K251577 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k251577/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 22, 2025
Decision date	Feb 6, 2026
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Augmented Reality Software S.L.**
Location	Salamanca, ES
Contact	Santiago González Izard
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Compliance4Devices**
Contact	Juan Tezak

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov