FDA 510(k) Premarket Notification

K254115 ArteraAI Breast

CLEARED

May 4, 2026
136 days to decision

K254115 · Product code: **SHW** · Pathology
Source: https://www.510kdatabase.net/k254115/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Dec 19, 2025
Decision date	May 4, 2026
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Statement

APPLICANT

Company	**Artera, Inc.**
Location	Los Altos, CA, US
Contact	Candice Bautista
510(k) history	2 submissions · 1 cleared · 2025-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k254115/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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