

**K252917 ATLAAS (Atraumatic Left Atrial Appendage System)
(AD)**May 22, 2026
252 days to decisionK252917 · Product code: **PZX** · Cardiovascular
Source: <https://www.510kdatabase.net/k252917/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Left Atrial Appendage Clip, Implantable (PZX)
Date received	Sep 12, 2025
Decision date	May 22, 2026
Days to decision	252 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genesee Biomedical, Inc.
Location	Denver, CO, US
Contact	James Cross
510(k) history	14 submissions · 14 cleared · 2005-2026

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