

K260792 AerFrame Patient Immobilization System (AFPIS)May 8, 2026
58 days to decisionK260792 · Product code: IYE · Radiology
Source: <https://www.510kdatabase.net/k260792/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Mar 11, 2026
Decision date	May 8, 2026
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stabilix, LLC
Location	Dallas, TX, US
Contact	Richard Westhoven
510(k) history	1 submissions · 1 cleared · 2026-2026

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