

K251992 ArmSure Fluoroscopic Positioning SystemFeb 11, 2026
229 days to decisionK251992 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k251992/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jun 27, 2025
Decision date	Feb 11, 2026
Days to decision	229 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Savfe Co. , Ltd.
Location	New Taipei City, TW
Contact	Hsiao Man Hsu
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251992/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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