

K253192 DeepXray SpinaJun 10, 2026
257 days to decisionK253192 · Product code: **SAO** · Radiology
Source: <https://www.510kdatabase.net/k253192/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiology Software For Opportunistic Evaluation Of Low Bone Mineral Density (SAO)
Date received	Sep 26, 2025
Decision date	Jun 10, 2026
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alpha Intelligence Manifolds, Inc.
Location	New Taipei City, TW
Contact	Qingzong TSENG
510(k) history	2 submissions · 2 cleared · 2023-2026

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