

K250850 Nanox.ARC XApr 16, 2025
27 days to decisionK250850 · Product code: **IZF** · Radiology
Source: <https://www.510kdatabase.net/k250850/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomographic (IZF)
Date received	Mar 20, 2025
Decision date	Apr 16, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nano-X Imaging , Ltd.
Location	Petah Tikva, IL
Contact	Ofir Koren
510(k) history	5 submissions · 5 cleared · 2021-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250850/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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