

K233080 HealthFLDFeb 8, 2024
135 days to decisionK233080 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k233080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Sep 26, 2023
Decision date	Feb 8, 2024
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nano-X AI , Ltd.
Location	Sefayim, IL
Contact	Neta Sherman
510(k) history	2 submissions · 2 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233080/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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