

K203782 Nanox Cart X-ray SystemApr 1, 2021
94 days to decisionK203782 · Product code: **IZL** · Radiology
Source: <https://www.510kdatabase.net/k203782/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Dec 28, 2020
Decision date	Apr 1, 2021
Days to decision	94 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Accelerated Device Approval Services
Contact	Rafael Aguila

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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