April 16, 2025

Nano-x Imaging Ltd.
℅ Noa First
Ragulatory Affairs Manager
94 Em Hamoshavot Road, Brosh building, Ofer Tech Park,
PO Box 3486
PETAH TIKVA, 4970602
ISRAEL

Re: K250850
Trade/Device Name: Nanox.ARC X
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic x-ray system
Regulatory Class: Class II
Product Code: IZF, MQB
Dated: March 20, 2025
Received: March 21, 2025

Dear Noa First:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Lu Jiang
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250850

Device Name

Nanox.ARC X

Indications for Use *(Describe)*

Nanox.ARC X is a stationary X-ray system intended to produce tomographic images for general use including human musculoskeletal system, pulmonary, intra-abdominal, and paranasal sinus indications, adjunctive to conventional radiography, on adult patients.

This device is intended to be used in professional healthcare facilities or radiological environments, such as hospitals, clinics, imaging centers, and other medical practices by trained radiographers, radiologists, and physicists.

Digital Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep. Applications can be performed with the patient in prone, supine, and lateral positions.

This device is not intended for mammographic, angiographic, cardiac, intra-cranial, interventional, or fluoroscopic applications. This device is not intended for imaging pediatric or neonatal patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

04/10/2024

510(k) SUMMARY

K250850

I. SUBMITTER

Applicant Name: NANO-X Imaging Ltd.

Applicant Address: 94 Em Hamoshavot Road, Brosh building, Ofer Tech Park,

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Applicant Contact: Ofir Koren, General Manager ARC Division

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Correspondent Contact: Noa First, Regulatory Affairs Manager

Correspondent Contact Email: noa.f@nanox.vision

II. DEVICE

Device Trade Name: Nanox.ARC X

Common Name: System, X-Ray, Tomographic

Classification Name: Tomographic x-ray system

Regulation Number: 892.1740

Product Code(s): IZF, MQB

III. PREDICATE DEVICE

Predicate #: K242395

Predicate Trade Name: Nanox.ARC

Product Code: IZF, MQB

IV. DEVICE DESCRIPTION

Nanox.ARC X is a stationary, floor-mounted, stand-alone digital tomosynthesis system intended to produce tomographic images for general use including human musculoskeletal system, pulmonary, intra-abdominal, and paranasal sinus indications, from a single tomographic sweep. It serves as an adjunct to conventional radiography, for adult patients in recumbent positions. The system is intended for use in professional healthcare settings such as hospitals, clinics, and imaging centers by trained radiographers, radiologists, and physicists

The Nanox.ARC X includes a secured, dedicated off-the-shelf handheld operator console, a multisource, tiltable arc gantry with five identical tubes, a motorized patient table, and a flat panel detector of a scintillator-photodetector type. The image reconstruction service and DICOMization services can be hosted either locally or as part of the secured Nanox.CLOUD, according to customer preference. Nanox.CLOUD also hosts a protocol database service package.

The Nanox.ARC X X-ray tubes are operated sequentially, one at a time, generating multiple low-dose images acquired from different angles, during a single sweep, dividing the overall power requirements among the tubes. The sweep is performed over a motorized patient table. Patients can be placed in prone, supine, and lateral positions.

The acquired projection imaging data is anonymized and automatically reconstructed to form tomographic slices of the imaged object, with each slice parallel to the table plane. The Tomosynthesis image result reduces the effect of overlying structures and provides depth information on structures of interest. The resultant images are re-identified and sent using the DICOM protocol.

V. INDICATIONS FOR USE

Nanox.ARC X is a stationary X-ray system intended to produce tomographic images for general use including human musculoskeletal system, pulmonary, intra-abdominal, and paranasal sinus indications, adjunctive to conventional radiography, on adult patients.

This device is intended to be used in professional healthcare facilities or radiological environments, such as hospitals, clinics, imaging centers, and other medical practices by trained radiographers, radiologists, and physicists.

Digital Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep. Applications can be performed with the patient in prone, supine, and lateral positions.

This device is not intended for mammographic, angiographic, cardiac, intra-cranial, interventional, or fluoroscopic applications. This device is not intended for imaging pediatric or neonatal patients.

VI. INDICATIONS FOR USE COMPARISON

The subject and the predicate devices have the same indications for use.

VII. TECHNOLOGICAL CHARACTERISTICS COMPARISON

Both the subject and predicate devices share the same fundamental operating and technological principles.

Both devices are tomosynthesis-based imaging systems designed to produce tomographic images of human anatomy, from a single tomographic sweep, adjunctive to conventional radiography, of adult patients in recumbent positions.

Both devices utilize sequentially activated cold-cathode X-ray sources, with identical internal tube geometry and spatial alignment with the same detector, and the Nanox.CLOUD reconstruction software.

The subject device maintains functional and technological equivalence to the predicate device while incorporating system-level refinements.

Technological Characteristics Comparison Table

Item	Subject Device K250850	Predicate Device K242395	SE Justification
System Architecture	System electronics internally arranged	System electronics externally arranged	**Similar** - Both system architectures retain the same functionality and components. Internalization of system electronics previously housed externally to improve system integration and fit within clinical environments; enhanced internal layout with no impact on system functionality
ARC Imaging Ring	Gantry-based arc structure with square-rounded design	Gantry-based arc structure with rounded design	**Similar** -Spatial configuration and internal geometry preserved; enclosure shape adjusted to optimize integration
Number of X-ray sources	Five (5), alternately-switched X-ray sources	Same	-
X-ray Tube Housing Material	Glass	Ceramic	**Similar** -Both systems utilize identical cathode technology, MEMS electron source, anode design, focal spot size, exposure parameters, X-ray field size, and target angle. Modification in housing material; no impact on emission characteristics, cathode technology, exposure range, or performance
Patient Weight Allowance	150kg / 330 lbs.	Same	-
Patient Table Footprint	Optimized footprint	Larger footprint	**Similar** -Both tables serve the same function and are motor-driven

All modifications have been verified and validated and do not impact safety or effectiveness.

VIII. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY & CONCLUSIONS

In order to support substantial equivalence, the following bench testing were performed on the subject device:

- System Electrical Qualification
- System Performance
- Longevity and Consistency
- Tube Longevity and Reliability
- Functional Verification
- Motion Control
- Dimensional and Mechanical Properties
- Image Quality
- Tube Comparison CEI and Nanox Korea
- Human Factors Summary
- Phantom Validation
- Weight Considerations
- Transportation
- Software Verification and Validation

In all instances, Nanox.ARC X System functioned as intended.

No clinical tests were performed for the subject device.

Based on performance data, the subject device was found to have a safety and effectiveness profile that is similar to the predicate device, demonstrating that the subject device is as safe, as effective, and performs as well as the predicate device.