



December 4, 2024

Nano-x Imaging Ltd.
% Odelia Maron
VP QA & RA
94 Em Hamoshavot Road, Brosh building,
Ofar Tech Park, PO Box 3486
Petah Tikva, 4970602
ISRAEL

Re: K242395
Trade/Device Name: Nanox.ARC
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic X-Ray System
Regulatory Class: Class II
Product Code: IZF, MQB
Dated: August 13, 2024
Received: November 15, 2024

Dear Odelia Maron:

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,

A handwritten signature in black ink that reads "Lu Jiang". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA".

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

Enclosure

Indications for Use

Submission Number (if known)

K242395

Device Name

Nanox.ARC

Indications for Use (Describe)

Nanox.ARC 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.

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Correspondent Contact	Dr. Odelia Maron
Correspondent Contact Email	Odelia.m@nanox.vision

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Nanox.ARC
Common Name	System X-Ray Tomographic
Classification Name	Tomographic x-ray system
Regulation Number	892.1740
Product Code(s)	IZF, MQB

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222934	Nanox.ARC	IZF

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

Nanox.ARC 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 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-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.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

Nanox.ARC 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.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

Device Intended Use, to produce tomographic images, remains the same as cleared under K222934. The Indications for Use have been expanded from musculoskeletal (MSK) imaging to general use including pulmonary, intra-abdominal, and paranasal sinus indications. This expansion does not alter the intended patient population, intended users, usage environments, adjunctive usage, or patient positioning. Importantly, this expansion does not introduce any new safety or effectiveness concerns, as demonstrated by the Company's clinical sample data.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject and the predicate device are the same stationary, stand-alone Tomosynthesis X-ray system. No technological differences exist between the subject and predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The non-clinical performance testing conducted on the predicate device submitted under K222934 remain applicable to the subject device. The following non-clinical and clinical performance testing was performed on the subject device:

- Clinical Sample Data evaluation
- Chest Phantom Validation
- Weight Considerations for Performance Testing
- System Performance

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

The provided performance testing data for the subject device demonstrate that Nanox.ARC can generate diagnostic-quality images for the expanded Indications for Use. This includes the evaluation of complex anatomical structures and abnormalities of various sizes and shapes.

Based on performance data, including clinical sample 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.