April 28, 2023

Nano-X Imaging Ltd.
℅ Odelia Maron
VP QA & RA
Communications Center, Bldg. C, Entrance 1
Neve Ilan, 9085000
ISRAEL

Re: K222934
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: March 27, 2023
Received: March 27, 2023

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Lu Jiang

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222934

Device Name
Nanox.ARC

Indications for Use *(Describe)*
Nanox.ARC is a stationary X-ray system intended to produce tomographic images of the human musculoskeletal system 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, pulmonary, intra-abdominal, 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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510(k) Summary

Nanox.ARC
510(k) Summary

K222934

1 Submission Sponsor

Nano-x Imaging Ltd.
Communications Center, Bldg. C, Entrance 1,
Neve Ilan, Israel 9085000
Establishment Registration Number: The Company will register following FDA clearance

2 Submission Correspondent

Odelia Maron, Ph.D. VP QA & RA
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3 Date Prepared

March 24, 2023

4 Device identification

Name of Device:	Nanox.ARC
Classification Name:	Tomographic X-ray System
Regulation:	21 CFR §892.1740
Regulatory Classification:	Class II
Product Classification Code:	IZF and MQB
Classification panel:	Radiology

5 Legally Marketed Predicate and Reference Device

Predicate Manufacturer:	AGFA NV.
Predicate Trade Name:	DR 600 with Tomosynthesis
Predicate Classification Code:	IZF and MQB
Predicate 510(k):	K193262
Reference Manufacturer:	AGFA NV.
Reference Trade Name:	DR 800 with Tomosynthesis
Reference Classification Code:	IZF and JAA
Reference 510(k):	K183275

6 Device description

Nanox.ARC is a tomographic and solid-state X-ray system (product codes IZF and MQB) intended to produce tomographic images of the human musculoskeletal system from a single tomographic sweep, as an adjunct to conventional radiography, on adult patients.

Nanox.ARC is a floor-mounted tomographic system that consists of a user control console, a multi-source, tiltable arc gantry with five alternately-switched tubes, a motorized patient table, a flat-panel detector of a scintillator-photodetector type, and Protocols database and Image processing software packages.

Nanox.ARC utilizes several small-sized X-ray tubes that are independently and electronically switched, thereby dividing the overall power requirements over multiple tubes. Nanox.ARC utilizes a tilting imaging ring with five X-ray tubes, operated sequentially, one at a time, used to generate multiple low-dose X-ray projection images acquired from different angles during a single spherical (non-linear) sweep. 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 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 image reconstruction service, as well as the system's protocol database and DICOMization

services, can be hosted either locally or as part of the Nanox.CLOUD, according to customer preference. The resultant images are sent using the DICOM protocol.

7 Indications for Use

Nanox.ARC is a stationary X-ray system intended to produce tomographic images of the human musculoskeletal system 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, pulmonary, intra-abdominal, intra-cranial, interventional, or fluoroscopic applications. This device is not intended for imaging pediatric or neonatal patients.

8 Technological Characteristics

Nanox.ARC is a stationary X-ray tomographic system utilizes predefined protocols with predefined optimal acquisition parameters depending on the anatomy being imaged. The System allows the user to further configure these parameters for each examination type.

The acquired projection imaging data is automatically reconstructed to form tomographic imaged object.

A reconstruction engine converts the 2D images from the detector into Tomographical layers data. This reconstruction engine, as well as the system's protocol database and DICOMization services, can be hosted either locally, or as part of the Nanox.CLOUD.

9 Substantial Equivalence

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence with respect to indications for use, principles of operation, technological characteristics, materials, and performance.

The comparison of the devices in Table 1 below provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new or different questions of safety or effectiveness based on the similarities to the predicate device.

Table 1 – Comparison of Subject Device with Predicate Device

Item	**Subject Device** **Nanox.ARC**	**Predicate Device** **DR 600 with Tomosynthesis**
Name	Nanox.ARC	DR 600 with Tomosynthesis
Manufacturer	Nano-x Imaging Ltd.	AGFA NV
510(k)	K222934	K193262
Date of clearance	To be assigned	March 9, 2020
Indications for use	Nanox.ARC is a stationary X-ray system intended to produce tomographic images of the human musculoskeletal system 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, pulmonary, intra-abdominal, intra-cranial, interventional, or fluoroscopic applications. This device is not intended for imaging pediatric or neonatal patients.	The DR 600 System is a general radiography X-ray imaging system used in hospitals, clinics and medical practices by radiographers, radiologists and physicists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult, pediatric or neonatal patients. In addition, the System provides the AGFA tomosynthesis option, intended to acquire tomographic slices of human anatomy and to be used with AGFA DR X-ray systems. Digital Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep. Applications can be performed with the patient in a sitting, standing or lying position. This System is not intended for mammography applications.
Intended users	Radiographers, radiologists, and physicists	Radiographers, radiologists, and physicists
Intended use environment	Hospitals, clinics, imaging centers, and other healthcare facilities	Hospitals, clinics, imaging centers, and other healthcare facilities
Classification Name	Tomographic X-ray system	Tomographic X-ray system
Regulation number	21 CFR § 892.1740	21 CFR § 892.1740
Regulatory class	II	II
Product code	IZF, MQB	IZF, MQB
General		
Principal operator	Radio Technician	Radio Technician

Item	Subject Device Nanox.ARC	Predicate Device DR 600 with Tomosynthesis
Communications with external storage devices	DICOM	DICOM
Patient positioning options		
Vertical stand	Not included	Included as an Option
Table stand	Included	Included as an Option
Patient Table		
Patient table height	48cm (motorized w/fixed height)	55-90 cm (motorized w/ height adjustment)
Patient weight allowance (kg/lbs.)	150kg / 330 lbs.	320 Kg / 705 lbs.
Table length (mm)	2600	2200
Table width (mm)	720	810
Tabletop material	PMMA	Resopal HPL (DIN EN438)
Generator		
Tube voltage range (kVp)	40-110	40-150
Nominal electric power (kW)	1.8	Selectable 50, 65 or 80
Total mAs range per Tomosynthesis study	12-90 mAs	12-90 mAs
X-ray accuracy	Fulfills the X-ray radiation accuracy according to EN IEC 60601-2-54 with a variation of max. 0.05 (5%).	Fulfills the X-ray radiation accuracy according to EN IEC 60601-2-54 with a variation of max. 0.05 (5%).
X-ray source		
Electron stream source	MEMS chip	Tungsten filament
Physical phenomena generating electron stream	Quantum tunneling via an applied External electrical field (cold cathode)	Thermionic excitation (Hot Cathode)
Focal spot size (nominal FS value large/small focus)	0.7	E7884X: 0.6/1.2 E7252X: 0.6/1.2 E7254FX: 0.6/1.2 E7869XX: 0.6/1.2
Anode design	Stationary Anode	Rotating Anode
Target angle	19 deg	12 deg
Source to Image Distance (SID)	Fixed (at 100cm)	Selectable (110cm/115cm) for Tomosynthesis. Other SIDs available for other procedures
X-ray source position	Table mounted	Ceiling or table mounted
Number of X-ray sources	Five (5) X-ray sources	One (1) X-ray source
Sweep angle during Tomosynthesis	Longitudinal: up to ±18° Lateral: up to ±15°	Longitudinal: selectable at ±15° or ±22°
Tilt mode	Automatic	Automatic
X-ray Field size		
X-ray field size	Fixed, 43x43 cm	Variable, between 1-43cm by 1-43cm
Visual indication of the X-ray field	Indication by a Graphical User Interface	Indication by a light-field indicator
Image Processing		
Detector	Flat-panel detector	Flat-panel detector
Operating System	Ubuntu 20.04 LTS	Windows® 7, 8, 8.1, 10
Operator Console	Tablet device (iPad)	PC
Imaging Protocols location	Either Local (hardware-based) or Cloud-based	Local (hardware-based)
Image processing location	Either Local (hardware-based) or Cloud-based	Local (hardware-based)

Item	Subject Device Nanox.ARC	Predicate Device DR 600 with Tomosynthesis
DICOM encapsulation service location	Either Local (hardware-based) or Cloud-based	Local (hardware-based)
Image processing package	Proprietary	AGFA's MUSICA² ™ image processing and AGFA's MUSICA Digital Tomosynthesis software (K193262) image processing
Compliance		
Human factors	IEC 62366 and FDA guidance	IEC 62366 IEC 60601-1-6
Biocompatibility	ISO 10993-1 and FDA guidance	ISO 10993-1 and FDA guidance
Electrical safety	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2
Radiation safety	IEC 60601-1-3 IEC 60601-2-54 IEC 60601-2-28	IEC 60601-1-3 IEC 60601-2-54 IEC 60601-2-28
Other standards	ISO 13485 ISO 14971 ISO 14155	ISO 13485 ISO 14971

10 Summary of Technical Characteristics comparison

The Nanox.ARC and the predicate device have similar intended use with regard to their respective indications for the production of Tomosynthesis images. Both have similar technological characteristics, again, with regard to their respective indications for the production of Tomosynthesis images, and use the same principles of operation and are also identical in the following ways:

- Regulation number - 21 CFR §892.1740
- Product Code - IZF and MQB
- Regulatory Class - Class II

In addition, both devices have equivalent technological characteristics, with the exception of:

- The Nanox.ARC utilizes five individual small-sized X-ray tubes, whilst the predicate utilizes one larger general-purpose X-ray tube. Both Systems share a similar dose range.
- In the Nanox.ARC, irradiations are done in a spherical path geometry, whereas in the predicate, irradiations are done in a linear path geometry.
- In the Nanox.ARC, table and gantry movements are limited to specific angles, SID, and positions, while in the predicate, the tube moves in tomographic sequence in the room.
- In the Nanox.ARC, The field size of the Nanox.ARC is non-adjustable and fixed at 43x43cm (17x17"), whereas the predicate X-ray field can be varied by the operator from 1x1cm to up to 43x43cm.
- In the Nanox.ARC, the generator has a lower power output (1.8kW) than the predicate's (50/65/80kW) and lower kVp and mAs ratings.
- In the Nanox.ARC, the mAs range per each tomosynthesis projection is lower than the predicate.
- In the Nanox.ARC, the protocol database, the image reconstruction and DICOMization services - are either based on local hardware or cloud-based, whereas for the predicate protocol database, these services are based on local hardware.
- In the Nanox.ARC, the control console is an off-the-shelf Tablet device, where in the predicate, the operator console is installed on an off-the-shelf PC.

These minor differences, both individually and as accumulated differences - do not present any new or different questions of safety or effectiveness as confirmed by the completed testing discussed in more detail below.

Thus, the Nanox.ARC is substantially equivalent to the DR 600 with Tomosynthesis by AGFA NV (K193262).

11 Performance Data

Laboratory testing and software testing (for a moderate level of concern device) using equivalent test protocols were evaluated by qualified individuals to demonstrate that adequate design controls (according to 21 CFR 820.30) were in place.

Verification and validation testing confirmed the device meets performance, safety, usability and security requirements. Results were verified and validated.

The performance characteristics and operation / usability of Nanox.ARC were evaluated in non-clinical (bench) testing. These studies have demonstrated the device related performance, overall function, verification and validation of requirements for intended use, and reliability of the system software requirements.

Non-clinical test results have demonstrated that the device conforms to its specifications. Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

A clinical sample evaluation by an ABR-certified radiologist was completed to evaluate the imaging performance of Nanox.ARC.

The objective of the evaluation was to define whether Nanox.ARC Tomosynthesis, when performed as an adjunct to conventional radiography of the musculoskeletal system, is of diagnostic quality.

This evaluation was done against a reference comparison which was the standard of care radiographies.

Nine (9) Digital Tomosynthesis image cases were acquired from healthy adult human subjects (patients) from a clinical study conducted at Shamir Medical Center in Israel.

In addition, twelve (12) Digital Tomosynthesis phantom performance exams were captured. The acquired clinical exams met the inclusion/exclusion criteria. X-ray images were acquired using appropriate device dependent exposure for Digital Tomosynthesis acquisitions.

12 Bench Testing

Bench tests were performed in a laboratory setup, demonstrating that the Nanox.ARC device meets all specifications as required for intended use. All tests were performed in accordance with written protocols using calibrated equipment.

The set of non-clinical evaluations was conducted on assembled Nanox.ARC device units or (where applicable) system components. The bench tests were based on applicable standards and guidance documents and Company-conducted risk analysis activities.

The tests summarized below include methods, procedures, acceptance criteria, results, and conclusions. All design control documents, including test reports, are referenced on file at Nano-X Ltd. in accordance with 21 CFR 820.30.

The following tests were performed:

Table 2: Non-clinical Performance Data

Test	Test description	Result
System Electrical Qualification	Verify that Nanox.ARC electrical qualification is according to system	PASS
System Performance	Evaluate Nanox.ARC motion resolution and accuracy performance	PASS
System Longevity & Consistency	Verify that the Nanox.ARC Table and ARC lifetime and consistency is according to system spec.	PASS
Tube Longevity and Reliability	Verify that the Nanox.ARC Tubes lifetime and consistency is according to System spec.	PASS
Functional Verification	Verify that the Nanox.ARC Tubes' lifetime and consistency are according to system spec.	PASS
Motion Control	Verify the stability of Nanox.ARC motion in precise linear and angular movements is according to specification	PASS
Detector and image acquisition	Verify the key functionality of the detector as well as the system imaging properties.	PASS
Usability Summative	Demonstrate that after training, when used by intended users in the expected use environment, the Nanox.ARC system can be used safely and effectively without producing patterns of failures that could result in negative clinical impact, injury to patients and users, or damage to the device. Tested using FDA guidance, IEC 62366-1 and ISO 14971	PASS
Transportation	Ensure the packing allows for safe transportation of the Nanox ARC while preventing damage to it, using ASTM D4169; ISTA 1H; IEC 60068-2; IEC 60068-2-64	PASS
Dimensional and Mechanical Properties	Verify Dimensional and Mechanical properties of Nanox.ARC system as defined in System requirement Specification documentation.	PASS
Image Quality	Verify that the key functionality of the detector as well as the system imaging properties is as defined in System requirement Specification documentation:	PASS
Phantom Validation	Evaluation of the system performance in comparison with the predicate system in terms of diagnostic quality.	PASS
Software verification and validation using FDA Guidance; IEC 62304	The device meets design and cybersecurity requirements	PASS
21 CFR 1020.30 and 21 CFR 1020.31	Nanox.ARC is compliant to the FDA Subchapter J mandated performance standard	PASS
Electrical Safety & EMC IEC 60601-1 IEC 60601-1-2	Conformance to electromagnetic compatibility standards, accompanied by certificate	PASS
Radiation Safety IEC 60601-1-3 IEC 60601-2-28 IEC 60601-2-54	Conformance to electromagnetic compatibility standards, accompanied by certificate	PASS
Biocompatibility using FDA guidance, ISO 10993-1	Conformance to recognized biocompatibility standards supported by Biological Risk Assessment.	PASS

13 Substantial Equivalence Conclusions

Utilizing FDA's Substantial Equivalence Decision Flowchart, the following was concluded:

- The subject device has the same intended use and similar indications for use as the predicate device
- The subject device has similar technological characteristics to the predicate device
- The different characteristics do not raise new or different safety or effectiveness questions
- Acceptable scientific methods exist for assessing the new characteristics

- Performance data are available to assess the effects of the new characteristics
- Performance data and phantom testing (together with descriptive characteristics) demonstrate substantial equivalence

Review of performance lab, bench, and user testing results, as well as comparison of the device classification, indication for use, operating principles, and technological characteristics, demonstrate that the subject device is substantially equivalent to the predicate DR 600 with Tomosynthesis by AGFA NV (K193262). Any differences between the subject and predicate device do not raise new questions of safety or effectiveness.