Nano-x Imaging Ltd.
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services
6800 S.W. 40th Street, Ste. 403
LUDLUM FL 33155

April 1, 2021

Re: K203782
Trade/Device Name: Nanox Cart X-ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: March 1, 2021
Received: March 24, 2021

Dear Rafael Aguila:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K203782

Device Name
Nanox Cart X-Ray System

Indications for Use *(Describe)*
The product is intended as an X-Ray source for diagnosis. Operators of the Nano-x Cart X-Ray System are healthcare professionals familiar with and responsible for the X-Ray examinations being performed.

Indication for Use – The device is designed to perform radiographic X-Ray examinations of hands, wrists, and fingers, on adult patients.

Limitations for use – This device is not intended for general radiographic X-Ray examinations other than the indicated use, or for mammographic, angiographic, interventional, or fluoroscopic applications. This device is not intended for pediatric use.

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 K203782

Applicant: Nano-x Imaging Ltd.
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Date Prepared: Mar. 1, 2021

Device Trade Name:	Nanox Cart X-Ray System
Device Common Name:	Mobile X-Ray Device
Classification Name:	Mobile X-Ray system
Regulation Number:	21 CFR 892.1720
Regulation Class:	II
Product Code:	IZL

Predicate Device:	AMX-4 Mobile X-Ray System
Manufacturer:	GE Medical Systems
510(k) Number:	K021016
Regulation Name:	Mobile x-ray system
Number:	21 CFR 892.1720
Regulatory Class:	II
Product Code:	IZL

Reference Device:	DRX-Revolution Nano Mobile X-ray System
Manufacturer:	Carestream Health Inc.
510(k) Number:	K173924
Regulation Name:	Mobile x-ray system
Number:	21 CFR 892.1720
Regulatory Class:	II
Product Code:	IZL

Device Description:

The Nanox Cart X-Ray system is a mobile X-Ray system designed to perform radiographic X-Ray examinations of hands, wrists, and fingers, on adult patients. The system facilitates X-ray examinations in situations where it is not possible or feasible to transport the patient to a ward with fixed equipment.

The Nanox Cart X-Ray system consists of a mobile system enclosure; an X-Ray tube assembly consists of the X-ray Tube, Cooling Fluid, electronics, and casing; a pulse generator and a high-voltage generator; a microprocessor that provides increased exposure consistency and efficient operation; and a touch-based screen LCD which provides a simple and user-friendly interface and technique selection.

The Nanox Cart is specified and designed to operate only with a Flat Panel Digital X-ray Detector Model EVS3643, manufactured by DRTECH Inc. (K162552)

The intended operators of the Nanox Cart X-ray System are healthcare professionals familiar with and responsible for the X-ray examinations being performed.

To minimize electrical, mechanical, and radiation hazards, the Nanox Cart X-ray System adheres to recognized and established industry practices and standards.

Intended Use/Indications for Use:
The product is intended as an X-Ray source for diagnosis. Operators of the Nano-x Cart X-Ray System are healthcare professionals familiar with and responsible for the X-Ray examinations being performed.

Indication for Use – The device is designed to perform radiographic X-Ray examinations of hands, wrists, and fingers, on adult patients.

Limitations for use – This device is not intended for general radiographic X-Ray examinations other than the indicated use, or for mammographic, angiographic, interventional, or fluoroscopic applications. This device is not intended for pediatric use.

Summary of Technology Characteristics:
Table 1 provides a comparison of the technological characteristics for the Nanox Cart X-Ray System and the predicate device.
Table 2 provides a comparison of the technological characteristics for the Nanox Cart X-Ray System and the reference device.

Table 1: Comparison of Technological Characteristics

	Nanox Cart X-Ray System (K203782)	AMX-4 Mobile X-Ray System (K021016)	Significant Difference
Regulatory			
510(k)	K203782	K021016[1]	
Device class	II	II	Same
Classification	Mobile x-ray system, Class II; 21 CFR 892.1720	Mobile x-ray system, Class II; 21 CFR 892.1720	Same
Product code	IZL	IZL	Same
Indications / Intended use	The device is designed to perform radiographic X-Ray examinations of hands, wrists, and fingers, on adult patients.	The AMX-4 Plus Mobile X-ray System is indicated for use in generating radiographic images of human anatomy in all general-purpose X-ray diagnostic procedures. It may be used in radiology departments, emergency rooms, intensive care units, operating rooms, pediatrics, orthopedics, and clinics.	Similar
Intended users	X-ray Technicians trained to operate the system	X-ray Technicians trained to operate the system	Same
Physical Characteristics			
System Components	The Nanox Cart X-Ray System is comprised of the following components: 1) **Cart** – The mobile enclosure of the system. 2) **Wheels and Breaks** – Set of 4 (four) wheels and integral breaks that are placed to enable the mobility of the cart and have a stationary positioning during operation (cart will not be operated during movement). 3) **On/Off Switch** – A switch that switches the system on. 4) **X-Ray Stop** (Emergency Stop) – An emergency stop	The AMX-4mobile X-ray system is comprised of the following components: **1) Cart** **2) Collimator** **3) Column** **4) Power Connectors** **5) Rotating Arm** **6) Docking tube and docking receiver** **7) E-Stop (Emergency Stop) knobs** **8) Grid alignment system** **9) PREP/EXP switch** **10) Screen** **11) Tube head assembly** 12) **X-Ray Tube**	Similar

[1] https://www.accessdata.fda.go, v/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K021016

	Nanox Cart X-Ray System (K203782)	AMX-4 Mobile X-Ray System (K021016)	Significant Difference
	that prevents the system from operating, should the operator determine to halt procedure. 5) **X-Ray Switch** – A switch that enables the X-ray radiation energy. 6) **Display** – Operators display of energy emitted by the Nanox Cart. The display is a touchscreen that enables adjusting the energy pulse (touchscreen) from 0.1mAs up to 2mAs in steps of 0.1mAs. 7) **Controller** – the Display and a micro-controller (Arduino Mega 256) controls the Nanox Cart X-ray System's functionality and GUI display. 8) **Pulse Generator** – The pulse generator enables a pulse of 40kVp and 0.1—2mAs. 9) **Isolation Transformer** – Enables protection from power mains surges. 10) **Power Supply** – Power mains input of 230VAC/50Hz/300W. 11) **Tube Assembly** – The X-ray tube assembly consists of the X-ray Tube, Cooling Fluid, electronics, and casing to enable the emission of the radiation energy. 12) **X-ray Tube** – Nano-x's Cold Cathode tube.		
Imaging Radiographic film cassette	The Nanox Cart is specified and designed to operate only with a Flat Panel Digital X-ray	Any commercially available Radiographic film cassette	Different

	Nanox Cart X-Ray System (K203782)	AMX-4 Mobile X-Ray System (K021016)	Significant Difference
	Detector Model EVS3643, manufactured by DRTECH Inc. (K162552)		
Technology			
Principles of Operation	The positions of the Tube Assembly and detector holder are prefixed. The technician positions the patient's hand inside the indicated irradiation area on the detector. The technician sets the required energy on the Display's touchscreen. Irradiation energy is set with a fixed radiographic output voltage of 40kVp and a variable charge of 0.1—2mAs. Exposure time varies from 50ms up-to 1s (non-selectable). Once energy is set, the technician operates the system by pressing the X-Ray switch.	The technician has the ability to position the AMX-4's tube assembly using the rotating arm. The AMX-4 is an all-inclusive device, where X-ray images are constructed on its Display. The AMX-4 has a rechargeable array of 12.9V batteries that has the ability to operate the following methods: 1. Two 70 kVp, 10 mAs X−ray exposures, >7 seconds of preparation, > 25 seconds of field light, 5 minutes of drive time, 9 minutes of idle time 2. The AMX 4 batteries will provide enough capacity for 165 or more 100 kVp, 100 mAs X−ray exposures. Each exposure includes 4 seconds of preparation time and 30 seconds of idle time for battery recovery. This number may be reduced by additional idle time required for X−ray tube cooling.	Different
System Power	240 VAC, 50 Hz	100/200 VAC, 50/60 Hz	Same
Battery Powered	No	Yes	Different
kV Range	40 kVp	50-125 kVp, in 24 steps	Different
mAs Range	0.1 to 2mAs, in 0.1mAs step	0.40 to 320 mAs, in 30 steps	Different
Tube Type/Model	Nanox Tube	GE X-Ray tube model HRT09	Similar
Focal Spot	0.3 mm	0.6/2.0 mm	Similar
Target Angle	0 degrees	15 degrees	Similar
Column Rotation Range	Fixed	(+/-)270 degrees	Different

	Nanox Cart X-Ray System (K203782)	AMX-4 Mobile X-Ray System (K021016)	Significant Difference
Max Speed (kph)	4	4.8	Similar
Horizontal Travel (cm)	Fixed	40.6	Different
Vertical Travel (cm)	Fixed	138.4	Different
Maximum Tube Voltage	40 kV	100 kV	Different
Aperture shape	Rectangular	Rectangular	Same
Aperture Control	Fixed	Operator Adjustable	Different

Table 2: Subject and Reference Device (DRX-Revolution Nano X-ray system) Comparison

	Nanox Cart X-Ray System (K203782)	DRX-Revolution Nano X-ray system	Significant Difference
Regulatory			
510(k)	K203782	K173924	
Device class	II	II	Same
Classification	Mobile x-ray system, Class II; 21 CFR 892.1720	Mobile x-ray system, Class II; 21 CFR 892.1720	Same
Product code	IZL	IZL	Same
Indications / Intended use	The device is designed to perform radiographic X-Ray examinations of hands, wrists, and fingers, on adult patients.	The device is designed to perform radiographic x-ray examinations on pediatric and adult patients, in all patient treatment areas.	Similar
Intended users	X-ray Technicians trained to operate the system	X-ray Technicians trained to operate the system	Same
Technology			
System Power	240 VAC, 50 Hz	100 – 240 V, 50/60 Hz	Same
Power output	0.08kW	Maximum 4.8 kW @ 104 msec and 7.7 kW @ 13 msec of power	Similar
Nominal Voltage Output	40kVp	40 kVp to 110 kVp	Similar
Nominal mAs	0.1/2mAs	0.2 mAs to 20 mAs	Similar
kV Range	Fixed: 40 kVp	40 kVp to 110 kVp	different
mAs Range	0.1 to 2mAs, in 0.1mAs step	0.2 to 20.0 mAs	Similar
Tube Type/Model	Nanox Tube	Xinray CNT Tube	Similar

Tube Weight	0.4 kg	1.1 kg	Similar
Focal Spot	0.3 mm	0.9 mm to 1.9 mm	Different
Target Angle	16 deg	14deg	Similar

Performance Data

Bench testing

The complete system has been assessed and tested at the factory and by Standards testing facilities. The System passed all predetermined testing criteria. The Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by Nano-x, and followed the process documented in the System Validation Test Plan. Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

The following Standards were used to test the System, has met all the requirements listed in the Standards except for inapplicable requirements (which are listed in the various test reports):

- Nanox Cart X-Ray System Verification testing
- Software verification and validation (ISO 62304:2006 + A1:2015)
- Preclinical Comparison Tests
- Ergonomic testing (IEC60601-1-6, IEC62366)
- Electrical Safety Testing (IEC 60601-1, IEC 62304:2006 + A1:2014)
- Electromagnetic Compatibility (IEC 60601-1-2 Ed. 4)
- IEC/EN 60601-1: 2005 + AMD1: 2012 (3.1 Ed.) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-3: 2008 + AMD1: 2013 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-28:2017 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-54:2009+AMD1:2015+AMD2:2018 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

in accordance with section 514(c)(1)(A) of the FD&C Act as outlined in "Medical X-ray Imaging Devices: Conformance with IEC Standards," dated May 2019.

The diagnostic imaging performance of the Nanox Cart X-Ray system was evaluated by executing a phantom imaging study. The phantoms used for the imaging study were commercial products manufactured by Kyoto Kagaku and intended for X-Ray imaging tests. The phantoms represent different hands and are anthropomorphic both in appearance, size, and X-Ray attenuation characteristics.

Performance output shows that the Nanox Cart is capable of supplying X-Rays to generate radiographies. Professional evaluation of the output and professional comparison between the Nanox Cart X-Ray system and predicate device's output demonstrate that the outcome images of the Nanox Cart X-Ray system are as good as an X-Ray system available in market. Based on the clinical evaluations of three experts it can be concluded that the Nanox Cart X-Ray system operates as intended and generates images that are as good as images produced by the predicate Device.

Clinical testing

Nano-x Imaging Ltd. does not believe that clinical data is necessary to support the determination that the Nanox Cart X-ray System is substantially equivalent to the predicate. The bench testing described above is very comprehensive and demonstrates that the system meets its performance specifications. Specifically, the bench testing demonstrated the ability of the system to emit X-ray radiation as determined in its specifications.

The testing demonstrated that the product meets its performance specifications and performs as intended. In addition, the Nanox Cart X-Ray System was found to be substantially equivalent to the predicate device as it has the same indications for use and compliance with similar standards.

Substantial Equivalence Discussion:

The indications for use for the predicate device are similar to the proposed indications for use for the Nanox Cart X-Ray System. The technical characteristics of the System are not different from the predicate device except for the fixed Source-to-image Distance, Field of view, aperture, focal spot size, and the fixed Tube voltage and reduced maximum exposure current-time product. As demonstrated in Table 1 above, any differences in the technological characteristics do not raise any questions of safety or effectiveness.

The generated X-ray beams by both devices are the same, resulting with similar images generated by the devices. Thus, rendering the Nanox Cart X-Ray System substantially equivalent to the predicate device.

Conclusions

Extensive bench testing was conducted, which demonstrated that the Nanox Cart X-Ray System meets its performance specifications. This collection of testing demonstrates the safety and effectiveness of the Nanox Cart X-Ray System and its substantial equivalence to the predicate device.