February 2, 2026

Nano-X Imaging Ltd.
℅ Noa First
Regulatory Affairs Manager
94 Em Hamoshavot Road
Brosh Building, Ofer Tech Park, PO Box 3486
Petah Tikva, 4970602
ISRAEL

Re: K252649
Trade/Device Name: TAP2D
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic X-Ray System
Regulatory Class: Class II
Product Code: IZF, MQB, LLZ
Dated: December 31, 2025
Received: December 31, 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,

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252649

Device Name
TAP2D

Indications for Use *(Describe)*
TAP2D is a cloud-based software-module accessory intended exclusively for use with the Nanox.ARC X and Nanox.ARC systems, consistent with their cleared indications for use.

TAP2D is intended to provide a supplemental processed and enhanced 2D view image in DICOM format of a single 2D projection extracted from the acquired DTS study.

TAP2D is specifically indicated for assisting radiologists when evaluating diagnostic tomosynthesis studies and reaching their own diagnosis.

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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01/29/2026

510(k) SUMMARY

I. SUBMITTER

Applicant Name: NANO-X Imaging Ltd.

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II. SUBJECT DEVICE

Device Trade Name: TAP2D

Regulation Name: Tomographic X-ray System

Common Name: System, X-Ray, Tomographic

Regulation Number: 21 CFR 892.1740

Product Code(s): IZF, MQB, LLZ

III. PREDICATE DEVICE

Predicate #: K250850

Predicate Trade Name: Nanox.ARC X

Product Code: IZF, MQB

IV. REFERENCE DEVICE #1

Predicate #: K100372

Predicate Trade Name: SafeCT

Product Code: LLZ

V. REFERENCE DEVICE #2

Predicate #: K160852

Predicate Trade Name: Zia™

Product Code: LLZ

VI. DEVICE DESCRIPTION

TAP2D is a cloud-based software-module accessory for Nanox.ARC X and Nanox.ARC systems. It provides a supplemental enhanced 2D view image in DICOM format, of a 2D projection extracted from the DTS study acquisition by these systems.

TAP2D image is intended for assisting radiologists when evaluating tomosynthesis studies, by providing an enhanced, high-contrast single-2D-view image of the DTS scan.

TAP2D image is clearly tagged as a supplemental view in DICOM and transmitted to PACS alongside the diagnostic DTS series.

VII. INDICATIONS FOR USE

TAP2D is a cloud-based software-module accessory intended exclusively for use with the Nanox.ARC X and Nanox.ARC systems, consistent with their cleared indications for use.

TAP2D is intended to provide a supplemental processed and enhanced 2D view image in DICOM format of a single 2D projection extracted from the acquired DTS study.

TAP2D is specifically indicated for assisting radiologists when evaluating diagnostic tomosynthesis studies and reaching their own diagnosis.

VIII. INDICATIONS FOR USE COMPARISON

TAP2D is a software accessory designed for exclusive use with the legally marketed predicate device Nanox.ARC X (K250850) and its equivalent device Nanox.ARC (K242395). It operates strictly within the clinical scope of the cleared ARC systems and does not expand or alter the original indications for use, target population, intended user group, use environment, or imaging workflow.

Accordingly, while the Indications for Use Statement for TAP2D is not identical to that of the predicate device, TAP2D indications do not introduce any new clinical claims and remains fully consistent with the labeling and clinical scope of the predicate device, nor do they affect the safety or effectiveness of the predicate device.

Both the subject and predicate devices share the same general intended use and are utilized in the same clinical context. Therefore, TAP2D and the predicate device Indications for Use and are substantially equivalent in terms of intended use, safety, and effectiveness.

IX. TECHNOLOGICAL CHARACTERISTICS COMPARISON

TAP2D functions as an accessory to the predicate device that introduces an additional, supplemental post-process output derived from existing data acquired by the predicate device. It does not alter or expend the predicate's functionality, does not alter raw data, and does not affect clinical performance.

Therefore, the technological characteristics of the subject device are consistent with those of the predicate, maintain functional and technological equivalence, and do not raise new or different questions of safety or effectiveness.

Technological Characteristics Comparison Table

Item	**Subject Device K252649**	**Predicate Device K250850**	**SE Justification**
SaMD?	Yes	No	**Different –** TAP2D is a software-module accessory (SaMD) intended exclusively for use with Nanox.ARC X and Nanox.ARC systems.
Image Acquisition	None – TAP2D performs no image acquisition; post-processing only	Integrated hardware-based image acquisition	**Different –** TAP2D does not interact with any X-ray hardware or performs image capture. It post-processes DTS acquisition data already acquired by the predicate device.
DICOM Output	Supplemental enhanced 2D view image of DTS series	DTS series	**Similar –** both outputs are in DICOM format, compatible with PACS. TAP2D adds a supplemental enhanced 2D view image extracted from DTS acquisition data. This output does not replace or modify the diagnostic DTS series.
Processing Location	Cloud-based processing via Nanox.CLOUD	Same	**Same –** TAP2D is deployed within the existing Nanox.CLOUD infrastructure of the predicate device.
User Interaction	None – fully automatic, no user interface	User interface for scan setup and DTS operation	**Different –** TAP2D module operates automatically, without requiring user interaction or manual activation and does not affect the existing user workflow of the predicate device.

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

To support Subject device's performance evaluation methodology, two reference devices, SafeCT (K100372) and Zia™ (K160852), were reviewed in addition to the predicate device Nanox.ARC X (K250850).

- SafeCT (K100372), A cleared software-only post-processing package that enhances CT images in DICOM format by reducing image noise.
- Zia™ (K160852), A cleared software-only image enhancement system designed to reduce noise in CT images and output images alongside the originals.

Reference devices were used in substantial equivalence determination to support the scientific rationale for phantom-based testing method, with adaptations appropriate for tomosynthesis imaging. Specifically, the verification approach was adapted from both predicate Nanox.ARC X device and Zia™, emphasizing phantom-based assessment to confirm image enhancement while preserving structural similarity. The validation approach followed the method used in SafeCT, focusing on radiologist evaluation of TAP2D and original images.

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

- Software Verification and Validation
- System Performance Verification
- Image Quality

In all instances, TAP2D module functioned as intended. Tests confirmed that TAP2D operates according to its specifications and produces the intended supplemental output without affecting predicate device’s diagnostic integrity, system safety, or workflow.

In addition, Subject device was cyber-tested as per the FDA guidance on Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (Document issued on June 27, 2025).

Further Clinical and Phantom Validation testing were performed on the subject device. The Company has validated the device performance through structured studies using both retrospective human clinical DTS data and anthropomorphic phantom images, acquired from Nanox systems. An independent, ABR certified radiologist reviewed the DTS scans with the corresponding, supplemental post-process TAP2D image to assess its impact when evaluating DTS studies. In addition, a comparison of the information presented in theTAP2D image with information presented in its corresponding clinical DTS study was performed to confirm that no findings, not shown on DTS, were introduced.

The results demonstrate that TAP2D supports radiologists when evaluating DTS studies without introducing diagnostic uncertainty.

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.