February 8, 2024

% Neta Sherman
AVP Regulatory Affairs and Quality
Shlomo Shmeltzer Road 94,
Petah Tikva, 4970602
PO BOX 3486
ISRAEL

Re: K233080
Trade/Device Name: HealthFLD
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: January 10, 2024
Received: January 10, 2024

Dear Neta Sherman:

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.

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)*
K233080

Device Name
HealthFLD

Indications for Use *(Describe)*
The HealthFLD device is an image processing software that provides quantitative and qualitative analysis of the liver from CT images to support clinicians in the evaluation and assessment of Fatty Liver. The HealthFLD software provides measurements of liver attenuation (mean HU in a region of interest). HealthFLD is indicated for use in non-contrast and contrast CT scans, with any clinical indication, for patients aged 18 up to 75. CTs must include a significant part of the liver. The HealthFLD device is not intended to provide a diagnosis or risk assessment of fatty liver disease.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary – HealthFLD

Nano-X AI Ltd.

510(k) Number - K233080

Applicant's Name: Neta Sherman, AVP Regulatory Affairs and Quality
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Tel: +972-3-7359202

Date Prepared: September 26, 2023

Trade Name: HealthFLD

Device:

Proprietary Name	Nano-X AI HealthFLD device
Premarket Notification	K233080
Classification Name	Computed tomography x-ray system.
Regulation Number	21 CFR §892.1750
Product Code	JAK
Regulatory Class	II

Predicate Device:

The HealthFLD device is substantially equivalent to the following Predicate Device:

Proprietary Name	Predicate Device: Nano-X AI HealthOST device
Premarket Notification	K213944
Classification Name	Computed tomography x-ray system.
Regulation Number	21 CFR §892.1750
Product Code	JAK
Regulatory Class	II

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Intended Use/Indication for Use:

The HealthFLD device is an image processing software that provides quantitative and qualitative analysis of the liver from CT images to support clinicians in the evaluation and assessment of Fatty Liver. The HealthFLD software provides measurements of liver attenuation (mean HU in a region of interest). HealthFLD is indicated for use in non-contrast and contrast CT scans, with any clinical indication, for patients aged 18 up to 75. CTs must include a significant part of the liver. The HealthFLD device is not intended to provide a diagnosis or risk assessment of fatty liver disease.

Device Description:

The HealthFLD device is an image processing software that provides quantitative and qualitative analysis of the liver from CT images to support clinicians in the evaluation and assessment of Fatty Liver.

The HealthFLD software provides measurements of liver attenuation (mean HU in a region of interest) for any compatible CT scan that includes a significant part of the liver

The Liver measurement display threshold is <40 HU for non-contrast/non portal venous phase CTs. When portal venous contrast phase is identified by the algorithm, the HealthFLD device automatically adjusts the display threshold to <75 HU.

The following modules compose the HealthFLD software:

1) **Data input and validation:** DICOM validation receives imaging study from hosting application and the validation feature assessed the input data (i.e. age, modality, view, etc.) to ensure compatibility for processing by the algorithm.
2) **HealthFLD algorithm:** Once a study has been validated, the algorithm analyzes the CT for analysis and quantification.
3) **IMA Integration feature:** The results of a successful study analysis is provided to the hosting application.
4) **Error codes feature:** In the case of a study failure during data validation or the analysis by the algorithm, an error is provided to the system.

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Technological Characteristics Compared to Predicate Device:

We believe that the HealthFLD device is substantially equivalent to the Nano-X AI HealthOST K213944.

	Proposed Device: **HealthFLD Device**	**Primary Predicate Device:** **Nano-X AI Ltd. HealthOST Device (K213944)**
Intended Use/ Indications for Use	The HealthFLD device is an image processing software that provides quantitative and qualitative analysis of the liver from CT images to support clinicians in the evaluation and assessment of Fatty Liver. The HealthFLD software provides measurements of liver attenuation (mean HU in a region of interest). HealthFLD is indicated for use in non-contrast and contrast CT scans, with any clinical indication, for patients aged 18 up to 75. CTs must include a significant part of the liver. The HealthFLD device is not intended to provide a diagnosis or risk assessment of fatty liver disease.	HealthOST is an image processing software that provides qualitative and quantitative analysis of the spine from CT images to support clinicians in the evaluation and assessment of musculoskeletal disease of the spine. The HealthOST software provides the following functionality: • Labelling of T1-L4 vertebrae • Measurement of height loss in each vertebra (T1-L4) • Measurement of the mean Hounsfield Units (HU) in volume of interest within vertebra (T11-L4) HealthOST is indicated for use in patients aged 50 and over undergoing CT scan for any clinical indication, that includes at least four vertebrae in the T1-L4 portion of the spine (for vertebral height loss) and T11-L4 (for bone attenuation) portions of the spine. The device is indicated for FBP-reconstructed images only

NANOXAI

Comparison of Technological Characteristics

Technological Characteristics	**Proposed Device:** **HealthFLD Device**	**Primary Predicate Device:** **Nano-X AI Ltd. HealthOST Device (K213944)**	**Summary**
Regulation			
Product Code	JAK	JAK	Same
Regulation Number	21 CFR §892.1750	21 CFR §892.1750	
General			
Modality	CT	CT	Same
Image format	DICOM	DICOM	Same
Supported CT scan	Non-contrast enhanced and contrast enhanced	Non-contrast enhanced and contrast enhanced	Same
Analysis and Measurement			
Detection of target organ	Yes, detection of the liver	Yes, detection of vertebras	Similar, both devices detect the target organ in the scan. The differences do not raise different questions of safety and effectiveness of the subject and predicate devices and evaluation of the device comprises the same types of verification and validation testing

Segmentation of organ	Deep-learning-based segmentation of the Liver	Deep-learning-based segmentation of vertebras	Similar, both devices perform segmentation of the target organ, in the same method. The differences do not raise different questions of safety and effectiveness of the subject and predicate devices and evaluation of the device 5-6comprises the same types of verification and validation testing
Measurement of Hounsfield (HU) value	HU measurements based on segmentation and mean HU in regions of interest (ROIs) Indication to user if outside reference range	HU measurements based on segmentation and mean HU in volume of interest Indication to user if outside reference range	Same, both devices measure mean attenuation (HU) of selected region within the organ Region of interest is equivalent to volume of interest
Reporting			
Device output	1. Annotation of up to three (3) Region of Interest (ROI) 2. Liver density measured in HU	1. Vertebrae label/name 2. Three (3) lines representing the anterior, middle, and posterior points measures, together with relative measurements 3. % Height loss and relative Genant category (20) 4. Bone density measured in HU	Similar, the subject device provides the analysis results as liver attenuation in HU, same as the predicate device provides the bone attenuation in HU.

Performance Data:

The HealthFLD was designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820.

Safety and performance of HealthFLD has been evaluated and verified in accordance with software specifications and applicable performance standards through Software Development and Validation & Verification Process to ensure performance according to specifications, User Requirements and Federal Regulations and Guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The HealthFLD device performance was evaluated in a stand-alone retrospective study of its performance compared to the established ground truth and respective to the predicate device. The objective of this study was to establish the safety, effectiveness and substantial equivalence of the HealthFLD software as compared to the predicate device (Nano-X AI Ltd. HealthOST, (K213944)). The HealthFLD overall performance was determined by comparing the device output measurements, to the ground truth measurements. The validation data-set included 250 cases.

The validation data-set included a truthed and enriched sample of 250 anonymized CT scans with at least 4 cm of liver from the superior aspect of the liver, from 4 healthcare institutions. The sample included sufficient representation from across the disease spectrum for the key measurement parameter provided by the device, namely mean liver attenuation (measured in Hounsfield Units). Ground truth measurements were determined by three US board-certified radiologists.

The validation data-set included 250 cases, of which the algorithm returned a result on 250 cases, a yield of 100%. Patient age ranged from 18-75 y.o (mean age of 51.7 years; SD=15.5) and 49% (122) were female. 50% of CTs were contrasts enhanced, and 62.25% (155) CTs were from U.S. data. The validation dataset represented the inclusion parameters, such as: Modality (CT), Axial orientation, Slice Thickness, and KVP.

The HealthFLD device demonstrated an overall agreement of 95.98% (95% CI: [92.77%, 97.8%] with the ground truth liver score binary classification of < 40HU versus ≥ 40HU and of 98.39% (95% CI: [95.94%, 99.37%]) with the binary classification liver score < 50HU versus ≥ 50HU, both exceeding the stated performance goal. The method comparison analysis demonstrated Bland-Altman 95% limits of agreement (LOAs) for the HealthFLD liver density bias versus the ground truth liver score of [-7.80HU, 7.00HU], which lie within the acceptance interval of [-10HU,10HU]. 94.78% (95% CI:[91.24%-97.19%]) of the differences between HealthFLD and the GT lie within the LOA which is substantially equivalent to the predicate device (K213944). The overall agreement for HealthFLD algorithm versus the ground truth identification of portal venous phase was 95.98%.

All CT data across the inclusion criteria were well supported by the HealthFLD device.

In conclusion, this study demonstrated the HealthFLD overall agreement and limits of agreement with respect to the ground truth liver measurements and establishes its safety and effectiveness, while demonstrating substantial equivalence to the predicate device. It also validated the performance of the HealthFLD device across important cohorts, and applicable subsets of imaging acquisition characteristics.

Conclusion:

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, HealthFLD device raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy and performance.

The results of the performance comparison study demonstrated that the HealthFLD device performs as intended, similarly to the predicate device. We can conclude that the HealthFLD device is as safe, as effective and performs at least as well as the predicate device.

The HealthFLD device is therefore substantially equivalent to the predicate device.