October 7, 2026

Vista AI, Inc.
James Rogers
Regulatory Affairs and Strategic Quality Assurance
702 Marshall Street Suite 280
Redwood City, California 94063

Re: K260092
Trade/Device Name: Vista AI Scan
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: September 8, 2026
Received: September 8, 2026

Dear James Rogers:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP), PCCP for Prescription and Image-Quality Assessment, Ver. 2. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,



Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260092

Please provide the device trade name(s).

Vista AI Scan

Please provide your Indications for Use below.

Vista AI Scan is an accessory to 0.55T, 1.5T and 3.0T whole-body magnetic resonance diagnostic devices (MRDD). It is intended to operate alongside, and in parallel with, the existing MR console to acquire traditional, real-time and accelerated images.

Vista AI Scan software controls the MR scanner to acquire, reconstruct and display static and dynamic transverse, coronal, sagittal, and oblique cross-sectional images that display the internal structures and/or functions of the entire body. The images produced reflect the spatial distribution of nuclei exhibiting magnetic resonance. The magnetic resonance properties that determine image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that may assist in the determination of a diagnosis.

Vista AI Scan is intended for use as an accessory to the following MRI systems:

Manufacturers:: GE Healthcare (GEHC), Siemens Healthineers
Field Strength:: 0.55T, 1.5T and 3.0T
GE Software Versions:: 12, 15, 16, 23, 24, 25, 26, 30
Siemens Software Versions:: N4/VE; NX/VA

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary
Vista AI Scan 3.4.0
K260092

Administrative Information

Submitter Name	Vista AI, Inc.
Submitter Address	702 Marshall Street Suite 280 Redwood City, CA 94063
Establishment Registration #	3011767965
Primary Contact	James Jochen Rogers FDA Regulatory Affairs, Quality Assurance, and Clinical Studies T: 724.713.2298 E: jr@vista.ai
Submission Date	Jan 12, 2026

Device Information

Trade / Proprietary Name	Vista AI Scan
Common Name	RTHawk
Product Version	3.4.0
Regulation Number	892.1000
Regulation Name	Magnetic resonance diagnostic device (MRDD)
Regulatory Class	Class II
Device Classification Name	System, Nuclear Magnetic Resonance Imaging
Classification Panel	Radiology
Classification Product Code	LNH

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Predicate Device(s)

510(k) #	Device	510(k) Sponsor	Clearance Date
K251029	Vista OS, Vista AI Scan, RTHawk	Vista AI, Inc.	August 21, 2025

Device Description

The Vista AI "Vista AI Scan" product provides a seamless user experience for performing MRI studies on GE and Siemens scanners. The underlying software platform that we use to accomplish this task is called "RTHawk".

RTHawk is a software platform designed from the ground up to provide efficient MRI data acquisition, data transfer, image reconstruction, and interactive scan control and display of static and dynamic MR imaging data. It can control MR pulse sequences provided by Vista AI and, on scanners that support it, it can equally control MR pulse sequences provided by the scanner vendor. Scan protocols can be created by the user that mix and match among all available sequences.

Vista AI Scan is an accessory to clinical 0.55T, 1.5T and 3.0T MR systems, operating alongside, and in parallel with, the MR scanner console with no permanent physical modifications to the MRI system required.

The software runs on a stand-alone Linux-based computer workstation with color monitor, keyboard and mouse. It is designed to operate alongside, and in parallel with, the existing MR console with no hardware modifications required to be made to the MR system or console. This workstation (the "Vista Workstation") is sourced by the Customer in conformance with specifications provided by Vista AI, and is verified prior to installation.

A private Ethernet network connects the Vista Workstation to the MR scanner computer. When not in use, the Vista Workstation may be detached from the MR scanner with no detrimental, residual impact upon MR scanner function, operation, or throughput.

RTHawk is an easy-to-use, yet fully functional, MR Operating System environment. RTHawk has been designed to provide a platform for the efficient acquisition, control, reconstruction, display, and storage of high-quality static and dynamic MRI images and data.

Data is continuously acquired and displayed. By user interaction or data feedback, fundamental scan parameters can be modified. Real-time and high-resolution image acquisition methods are used throughout RTHawk for scan plane localization, for tracking of

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patient motion, for detection of transient events, for on-the-fly, sub-second latency adjustment of image acquisition parameters (e.g., scan plane, flip angle, field-of-view, etc.) and for image visualization.

Vista AI Scan implements the conventional MRI concept of anatomy- and indication-specific Protocols (e.g., ischemia evaluation, valvular evaluation, routine brain, etc.). Protocols are pre-set by Vista AI, but new protocols can be created and modified by the end user.

Vista AI Scan Apps (Applications) are composed of a pulse sequence, predefined fixed and adjustable parameters, reconstruction pipeline(s), and a tailored graphical user interface containing image visualization and scan control tools. Vista AI Scan Apps may provide real-time interactive scanning, conventional (traditional) batch-mode scanning, accelerated scanning, or calibration functions, in which data acquired may be used to tune or optimize other Apps.

When vendor-supplied pulse sequences are used in Vista AI Scan, parameters and scan planes are prescribed in the Vista interface and images reconstructed by the scanner appear on the Vista Workstation. Vista AI Scan Apps and vendor-supplied sequences can be mixed within a single protocol with a unified user experience for both.

Machine Learning Use in Vista AI Scan

The AI algorithms within the Vista AI Scan system are designed to assist MRI technologists which are always in control of the scan process. The software automates aspects of MRI setup and parameter selection to help reduce exam time, simplify the workflow, and increase reliability. The AI models are employed to perform specific tasks such as:

- Prescription Localization: The AI provides an initial estimate of image prescriptions, which the technologist can adjust.
- Cardiac Segmentation: The AI provides measurements of the subject’s anatomy to aid in optimizing imaging parameters, which the technologist can modify.
- Artifact Detection: The AI alerts the technologist to poor image quality resulting from breathing artifacts, irregular rhythm, or inadequate DE myocardial nulling.
- Detection of Inadequate Inversion Time: The AI alerts the technologist to potentially inadequate myocardial nulling in delayed-enhancement imaging.
- Image Denoising: The AI improves image quality by removing image noise.
- Cardiac Motion Registration: The AI improves image quality by reducing motion across images when scanned in the cardiac short-axis view.

No clinical decisions are made by the software. The outputs of the AI models are imaging acquisition settings and preliminary analyses useful for assisting the acquisition of images,

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which are then visually presented to the technologist. The technologist retains the ability to reject or modify the AI's outputs.

The system uses neural networks for image analysis, with no generative AI employed. These models have a multi-layered architecture that reduces data to the most relevant set for inline image analysis.

Vista AI Scan operates compatible MR scanners within the safety parameters listed below:

Safety Parameter	Safety Level
Magnetic Field Strength	0.55T, 1.5T, 3.0T
Operating Modes	IEC 60601-2-33 1st Level Operating Mode
Safety Parameter Display	SAR, dB/dt
Max SAR	< 4 W/kg whole-body
Max dB/dt	1st Level Operating Mode

Indications for Use

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Vista AI Scan is intended for use as an accessory to the following MRI systems:

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Performance Data

Vista AI Scan was designed, developed, and validated to conform with all applicable requirements and standards to establish the device's safety and effectiveness. Quality assurance measures employed during the development of Vista AI Scan include:

- Code reviews
- Design reviews
- Unit and integration level testing
- Verification testing, including System and Manual testing
- Safety testing, including SAR, dB/dt, and acoustic noise
- Performance testing, including SNR and uniformity
- Validation testing

Vista AI has made general use of the FDA Recognized Consensus Standards listed in the table below, as applicable to device features and components:

Reference #	**Title**
IEC 60601-2-33:2022-08 (Ed. 4.0)	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis (radiology)
IEC 60601-1:2020 (Ed. 3.2)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; Section 14 Programmable Electrical Medical Systems (PEMS)
MS1-2008	Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
MS3-2008	Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
MS4-2010	Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices
MS8-2016	Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
NEMA PS3.1 - 3.20 (2023e)	Digital Imaging And Communications In Medicine (DICOM) Set
ISO 14971:2019	Medical Devices - Application Of Risk Management To Medical Devices

Tests conducted according to the above-referenced standards demonstrate that Vista AI Scan meets the requirements for its intended use and demonstrates substantial equivalence to the predicate device.

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Vista AI Scan AI Model Training and Verification

Vista AI Scan neural-network models were developed and trained using industry-standard methods for partitioning and isolating training, tuning, and internal testing datasets. Neural-network parameters and weights were updated on the training data and evaluated on the tuning data at each epoch. Upon full training, the model's generalizability was assessed on the independent internal testing dataset (preceding clinical verification). Model development data was partitioned by unique anonymous patient identifiers to prevent overlap across training, internal testing, and clinical verification datasets.

After training the Vista AI Scan models, clinical verification testing was performed for each new feature to assess clinical performance. Clinical assessments were performed by independent board-certified radiologists or cardiologists who were not involved in any aspect of model development (including providing labels for training, tuning or internal testing). Clinicians involved in clinical assessment were blinded to patient clinical information. Data used in clinical verification were obtained from multiple clinical sites representing diverse ethnic groups, genders, and ages. The clinical verification data was isolated from data used internally for training and tuning.

Summary of Clinical Verifications

Each AI-enabled module was independently validated on a test set held out from model development. The datasets, results, and validation methodology for each module are summarized below.

Automatic detection of poor myocardium nulling

Element	Detail
Summary test results	Test set accuracy 88.7% (95% CI: 79.0%-95.0%), sensitivity 80.0%, specificity 91.1%, false-negative rate 20.0%, false-positive rate 8.9%, ROC AUC 0.852.
Number of patients	Test: 36; Training: 237; Validation: 58 (total 331). Each imaging study is treated as one patient.
Number of samples & relationship	620 delayed-enhancement frames from 412 series / 331 studies — Training 455 frames (307 series / 237 studies); Validation 94 (67 / 58); Test 71 (38 / 36).
Demographics (gender/age/ethnicity)	Gender: approximately 57% male. Age range 13-87 years (median 67). Race/ethnicity: not captured.

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Element	Detail
Clinical subgroups & confounders	Manufacturer (GE, Siemens, Vista); field strength (0.55T / 1.5T / 3.0T); five delayed-enhancement sequence types. Reader additionally annotated per-frame signal-to-noise level and presence of clinically-relevant enhancement. Distributions matched between the pooled train+validation set and the test set (total-variation, chi-squared, and Jensen–Shannon divergences for categorical variables; 1-Wasserstein distance of 1.98 years for age).
Equipment & protocols	GE, Siemens, and Vista sequences; 0.55T/1.5T/3.0T; delayed-enhancement inversion-recovery frames (GRE and SSFP).
Reference standard (truthing)	One U.S. board-certified cardiologist (>5 years post-training) labeled each frame's TI acceptability (acceptable / not acceptable).
Test/training independence	Splitting performed at the study (session) level; the test set was held out from model development, and the decision threshold is the classifier's fixed neutral point (not selected from any split).

AI-based image denoising

Element	Detail
Summary test results	Average SNR improvement ~3.7×; image sharpness preserved (transition-width ratio ~1.00); Reader Study 1 (209 Vista series): zero cases of negative diagnostic impact, denoised preferred in 82.2%; Reader Study 2 (170 GE/Siemens/0.55T series): zero cases of negative diagnostic impact, denoised preferred in 97.4%.
Number of patients	Test: 77; Training: 82; validation: 13.
Number of samples & relationship	Training: 210 series from 82 patients (12,885 Cine Cartesian SSFP images); validation: 35 series from 13 patients. Test: 379 series from 77 patients (~4.9

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Element	Detail
	series per patient). 209 previously-cleared series (37 patients) plus 170 newly-added series (40 patients: 36 GE, 77 Siemens, 57 0.55T Vista). Reader Study 1 evaluated the 209 previously-cleared series; Reader Study 2 evaluated the 170 newly-added series.
Demographics (gender/age/ethnicity)	Gender approximately 67% male; age range approximately 20–85 years; individual race/ethnicity not captured.
Clinical subgroups & confounders	Sequence categories (Cine, Delayed Enhancement, Black Blood, Time-Course); field strengths 0.55T/1.5T/3.0T (predominantly 1.5T, ~65%); manufacturers Vista/GE/Siemens. Cross-category noise-distribution similarity confirmed.
Equipment & protocols	GE, Siemens, and Vista sequences; 0.55T/1.5T/3.0T; delayed-enhancement imaging with gadolinium contrast; four clinical sequence categories.
Reference standard (truthing)	Blinded reader study with three board-certified cardiologists; subjective diagnostic-quality assessment (paired negative-impact and best-overall-quality questions per case).
Test/training independence	Patient-level partitioning (all of a patient's images assigned to a single split); test data used once. Cross-sequence generalization from Cine-only training confirmed by noise-distribution metrics.

AI-based motion-artifact detection

Element	Detail
Summary test results	Sensitivity 85.2%, specificity 80.2%, PPV 67.6%, NPV 91.8%, accuracy 81.9%, false-negative rate 14.8%. One-sided 95% Clopper–Pearson bounds: accuracy lower bound 77.3%, false-negative-rate upper bound 22.9%. Stratified accuracy: GE 86.2%, Siemens 85.2%, Vista 75.3%; with consistent performance across manufacturer, field-strength, and artifact-type strata.

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Element	Detail
Number of patients	175. Patient-specific identifiers were not available in the anonymized data, so each study is treated as one patient.
Number of samples & relationship	Test: 248 gated Cartesian cine slices (81 graded by the reader as containing compromising motion artifact), from 175 studies (mean 1.42 slices per study, maximum 4). Balanced across manufacturer, field strength, and motion type: GE 94, Siemens 61, Vista AI 93.
Demographics (gender/age/ethnicity)	Gender: Approximately 63% male. Age: 12–87 years, median 58 (recorded for 166 of 175 studies). Race/ethnicity: not captured (removed by data anonymization prior to receipt).
Clinical subgroups & confounders	Manufacturer (Vista/GE/Siemens); field strength (0.55T/1.5T/3.0T); motion-artifact type (cardiac/respiratory).
Equipment & protocols	Vista, GE, and Siemens; 0.55T/1.5T/3.0T; gated Cartesian cine acquisitions.
Reference standard (truthing)	An independent board-certified cardiologist graded the test set fully blinded (without access to the model's predictions or the team's selection labels); the blinded grades serve as the reference standard. Test-set selection and labeling did not use model predictions at any stage.
Test/training independence	Test set held out from all training and tuning; studies disjoint at the patient level. Synthetic artifacts were used only during training, never in the test set.

Automatic Spine Localization

Element	Detail
Summary test results	In-vivo reader study: 100% of automated prescriptions rated acceptable for both cervical and lumbar. Retrospective validation additionally characterized per-parameter geometric error between the automated and clinically-acquired reference prescriptions (mean, standard deviation, and one-sided 95% confidence bounds).

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Element	Detail
Number of patients	Retrospective: 41 cervical and 42 lumbar subjects. In-vivo: 14 cervical and 12 lumbar subjects.
Number of samples & relationship	346 localizations (82 cervical + 264 lumbar), from 1,205 retrospective images (615 cervical + 590 lumbar).
Demographics (gender/age/ethnicity)	Cervical: Approximately 39.8% male; lumbar: approximately 53.2% male. Age ~8–87 years (cervical) and ~15–85 years (lumbar). Race/ethnicity reported at the site level across six sites (~40–56% White, ~20–54% Hispanic/Latino, ~2–21% Black, ~1–3% Asian & Pacific Islander), applied to the validation cohort via study-level assignment from the shared six-site pool.
Clinical subgroups & confounders	Scanner manufacturer (GE/Siemens); field strength (1.5T/3.0T); Cervical vs. lumbar (separately modeled and validated); prescription types (axial stack, sagittal stack, per-disc oblique axial).
Equipment & protocols	Multi-institutional clinical spine scans from six sites plus additional sources.
Reference standard (truthing)	Retrospective: the true scan-geometry parameters of the clinically acquired, radiologist-reported series (standard of care by construction), extracted deterministically from image geometry metadata. In-vivo: one board-certified radiologist with image order randomized and origin (manual vs. automated) blinded.
Test/training independence	Patient/study-level partitioning: all images from a patient study assigned to a single subset (train/tune/test).

The results above demonstrate that each module meets or exceeds its pre-specified acceptance criteria. All outputs are advisory; the trained operator retains final authority to accept, modify, or reject any prescription, quality flag, or image enhancement. On this basis the clinical performance of Vista AI Scan has been verified for its intended use and supports substantial equivalence to the predicate device.

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Technological Comparison to Predicate Device

Both the subject device and the predicate device software are intended as an accessory to 1.5T and 3.0T MRI systems, and are intended to integrate and interact seamlessly with the operating system software within those MRI systems. Both devices support all coils available on the specific installation's MRI console. Both devices support remote access to and imaging on the specific installation's MRI system.

The submitted Vista AI Scan software is comprised of the following functional modules which are also present in the predicate device:

- Acquisition - responsible for the transfer of MR raw data from the MR scanner to the Vista Workstation
- Analysis - contains the image post-processing tools
- Application - Vista APPs. Each APP is comprised of a pulse sequence, user parameters, a reconstruction pipeline, and a specific user interface
- Information System - the central repository of all relevant MRI system configuration, patient, study, scan, etc., parameters associated with the current patient study
- Reconstruction - responsible for the efficient processing of raw data to generate MR images via a flexible, pipelined topology
- Scan Control - responsible for low-latency network transfer of controlling orders for APPs, APPs parameters modifications, and dynamic information from the MR host in response to user or program requests
- Sequencer - creates and provides a specific set of pulse sequence waveforms to control the MR scanner
- Storage - obtains current patient and scan information, performs non-volatile local storage, exports images and data in DICOM format, and logs events.
- Visualization - implements all aspects of the user interface, including APP selection, controls to modify APP parameters, image display, image analysis, graphical slice prescription, and image review, save, and export.

As with the predicate device, Vista AI Scan Apps (Applications) are composed of a pulse sequence, predefined fixed and adjustable parameters, reconstruction pipeline(s), and a tailored graphical user interface containing image visualization and scan control tools. Vista AI Scan Apps provide real-time interactive, batch-mode, and accelerated scanning, as well as calibration functions, in which data acquired may be used to tune or optimize other Apps. Orthogonal, oblique, and double oblique imaging planes are fully supported. Vista AI Scan consists of a collection of default protocols containing a combination of Vista AI Scan Apps and vendor-provided pulse sequences, and functions and features of those Apps are unchanged from the predicate device.

In this submission, notable changes include:

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- Compatibility with 0.55T MRI scanners
- Automatic detection of poor myocardium nulling in short-axis DE scans
- AI-based image denoising applicable to cardiac images produced by GE and Siemens
- AI-based motion artifact detection applicable to cardiac cine images produced by GE and Siemens
- New Spine Localizer Apps designed to automatically localize several standard views in the spine
- A new Beating-Heart IR SSFP App provides inversion-recovery contrast similar to FB DE SSFP across multiple cardiac phases
- Integrated control and prescription of GE pulse sequences similar to the existing capability relative to Siemens pulse sequences.

Instructions for use are included within the device labeling, and the information provided enables the user to operate the device in a safe and effective manner.

The following compares the modified device to the predicate device K251029:

Attribute	**RTHawk 3.3.0, K251029**	**Vista AI Scan 3.4.0: Subject Device**
Device Name	Vista OS, Vista AI Scan, RTHawk	Vista AI Scan
Indications for Use	Vista OS is an accessory to 1.5T and 3.0T whole-body magnetic resonance diagnostic devices (MRDD). It is intended to operate alongside, and in parallel with, the existing MR console to acquire traditional, real-time and accelerated images. Vista OS software controls the MR scanner to acquire, reconstruct and display static and dynamic transverse, coronal, sagittal, and oblique cross-sectional images that display the internal structures and/or functions of the entire body. The images produced reflect the spatial distribution of nuclei exhibiting magnetic resonance. The magnetic resonance properties that determine image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that may assist in the determination of a diagnosis. Vista OS is intended for use as an accessory to the following MRI systems: Manufacturers:: GE Healthcare (GEHC), Siemens Healthineers Field Strength:: 1.5T and 3.0T GE Software Versions:: 12, 15, 16, 23, 24, 25, 26, 30 Siemens Software Versions:: N4/VE; NX/VA	Vista AI Scan is an accessory to 0.55T, 1.5T and 3.0T whole-body magnetic resonance diagnostic devices (MRDD). It is intended to operate alongside, and in parallel with, the existing MR console to acquire traditional, real-time and accelerated images. Vista AI Scan software controls the MR scanner to acquire, reconstruct and display static and dynamic transverse, coronal, sagittal, and oblique cross-sectional images that display the internal structures and/or functions of the entire body. The images produced reflect the spatial distribution of nuclei exhibiting magnetic resonance. The magnetic resonance properties that determine image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that may assist in the determination of a diagnosis. Vista AI Scan is intended for use as an accessory to the following MRI systems: Manufacturers:: GE Healthcare (GEHC), Siemens Healthineers Field Strength:: 0.55T, 1.5T and 3.0T GE Software Versions:: 12, 15, 16, 23, 24, 25, 26, 30 Siemens Software Versions:: N4/VE; NX/VA

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Scanner Compatibility	GE Healthcare, Siemens Healthineers	GE Healthcare, Siemens Healthineers
Magnetic Field Strengths	1.5T, 3.0T	0.55T, 1.5T, 3.0T
Pulse Sequences		
	B0 Mapping	B0 Mapping
	Brain Localizer	Brain Localizer
	Cardiac Localizer	Cardiac Localizer
	Cardiac T1 Map	Cardiac T1 Map
	Cardiac T2 Map	Cardiac T2 Map
	Cardiac T2* Map Spiral	Cardiac T2* Map Spiral
	Cardiac T2* Map Cartesian	Cardiac T2* Map Cartesian
	Cartesian Shimming	Cartesian Shimming
		Cervical Spine Localizer
	Cine Cartesian SSFP	Cine Cartesian SSFP
	Cine DE Cal	Cine DE Cal
	Cine Flow Calibration	Cine Flow Calibration
	Cine Spiral SSFP	Cine Spiral SSFP
	FB DE GRE Cal	FB DE GRE Cal
	FB DE GRE	FB DE GRE
	FB DE SSFP	FB DE SSFP
	FB MS Tagging GRE	FB MS Tagging GRE
	FB Multi-Slice GRE	FB Multi-Slice GRE
	FB Multi-Slice SSFP	FB Multi-Slice SSFP
	Frequency Scout	Frequency Scout
	Gated 3D MRA GRE	Gated 3D MRA GRE

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	Gated High-Res GRE	Gated High-Res GRE
	Gated Double-IR FSE	Gated Double-IR FSE
	HART GRE	HART GRE
	HART SSFP	HART SSFP
		IR SSFP Beating Heart
	Multi-Slice Cine Flow	Multi-Slice Cine Flow
	Multi-Slice DE GRE	Multi-Slice DE GRE
	Multi-Slice DE SSFP	Multi-Slice DE SSFP
	Nav 3D DE GRE	Nav 3D DE GRE
	Noise Measurement	Noise Measurement
	Prostate Localizer	Prostate Localizer
	Real-Time Loc GRE	Real-Time Loc GRE
	Real-Time Loc SSFP	Real-Time Loc SSFP
	Real-Time Color PC	Real-Time Color PC
	Single-BH 3D DE GRE	Single-BH 3D DE GRE
	Stack of Spiral Cine Flow	Stack of Spiral Cine Flow
		Thoracic Spine Localizer
	Time-Course GRE	Time-Course GRE
	Wait	Wait
Remote Imaging and Support	Yes	Yes
Automated Scan Planning	Yes	Yes
Predetermined Change Control Plan (PCCP)	No	Yes, allowing for updates to localizer and artifact-detection models

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Predetermined Change Control Plan

This Vista AI Scan version establishes a Predetermined Change Control Plan (PCCP) allowing for future controlled modifications to the automatic scan prescription and image-quality assessment models to include new anatomies and to improve their performance. These changes include machine-learning components trained under the guidance of appropriately skilled MR technologists and physicians. These changes enhance the performance of the software but do not change the existing intended use or indications for use.

Planned modifications under this PCCP are limited to either:

1. Changes to automatic scan prescription models that would add new semantic views to the model, either within an existing anatomic region or in a new anatomic region; or
2. Changes to image-quality assessment models to extend this capability to allow for image-quality assessments of additional image types.

Training procedures, neural-network architectures, and acceptance criteria for any device modification under this PCCP will be constrained to closely resemble those utilized in the corresponding features present in the cleared device. The testing of software changes within the scope of this PCCP will be performed within Vista AI's Quality Management System that is ISO 13485-certified. It will involve our existing, comprehensive testing procedures for those software components that are impacted by the change. In addition, clinical performance will be validated and assessed by US-based board-certified physicians skilled in the area relevant to the change. Changes will be deemed acceptable only when stringent acceptance criteria are met. For automated prescription features, the accuracy of models will be verified to be at least 80% or equivalent to the variability demonstrated among human operators. For image-quality assessment features, the model output must agree with clinician assessment at a rate of at least 80% with a false negative rate of no more than 20%.

All software changes that may be enabled under this PCCP will be incorporated into future versions beyond this 3.4.0 version. Customers will be informed of any such changes by Vista AI personnel prior to their installation. These changes represent modest modifications to our existing product and therefore do not impact the safety or effectiveness of the device for its intended use. Software updates under this PCCP will be treated as any other update of our cleared software, with relevant customers being notified of the availability of a new version and a summary of relevant changes provided to the user by Vista AI personnel.

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Conclusion

Based upon verification testing and compliance with voluntary standards, the Company believes that Vista AI Scan 3.4.0 is substantially equivalent to the predicate device, and does not raise any new questions of safety or effectiveness.