



August 21, 2025

Vista AI, Inc.
James Rogers
Regulatory Affairs and Strategic Quality Assurance
431 Florence Street
Suite 100
Palo Alto, California 94301

Re: K251029
Trade/Device Name: Vista OS, Vista AI Scan, RTHawk
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: April 2, 2025
Received: July 18, 2025

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.

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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue 'FDA' watermark.

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

510(k) Number (if known)

K251029

Device Name

Vista OS, Vista AI Scan, RTHawk

Indications for Use (Describe)

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

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

Vista OS; Vista AI Scan; RTHawk

K251029

Administrative Information

Submitter Name	Vista AI, Inc.
Submitter Address	431 Florence Street Suite 100 Palo Alto, CA 94301
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	April 2, 2025

Device Information

Trade / Proprietary Name	Vista OS, Vista AI Scan, RTHawk
Common Name	RTHawk
Product Version	RTHawk 3.3.0
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
K212233	RTHawk, HeartVista Cardiac Package	HeartVista, Inc.	October 5, 2021

Device Description

The Vista AI "Vista OS" 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.

RTHawk is an accessory to clinical 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 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.

RTHawk 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.

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

Machine Learning Use in Vista OS

The AI algorithms within the Vista OS 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 or irregular rhythm.
- 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, which are then visually presented to the technologist. The technologist retains the ability to reject or modify the AI's outputs.



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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.

RTHawk operates compatible MR scanners within the safety parameters listed below:

Safety Parameter	Safety Level
Magnetic Field Strength	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

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

Performance Data

Vista OS 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 OS 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 OS meets the requirements for its intended use and demonstrates substantial equivalence to the predicate device.



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Vista OS AI Model Training and Verification

Vista OS 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 OS 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

To test the automatic detection of motion artifacts in Cine Cartesian SSFP, 120 sample images collected from prior versions of Vista OS were assessed for the presence of clinically significant artifacts. Among images assessed, 81% were collected from male patients, 50% from 1.5 Tesla scanners, and 84% were scanned using GE scanners. Patient ages ranged from 20 to 80 years. Test data was segregated from training and tuning data and used only once in final clinical verification. The primary acceptance criterion for this test was 80% agreement between neural-network assessment at its default sensitivity level and the cardiologist reader.

To test the automatic detection of ungateable cardiac waveforms, 100 sample ECGs were assessed for suitability for a high-quality gated MR examination. Among waveforms assessed, 64% were collected from 1.5 Tesla scanners and 68% were collected using GE scanners. 37% of test waveform data did not specify a gender. Of the remaining 63%, 75% were collected from male patients. Patient ages ranged from 18 to 100 years. Test data was segregated from training and tuning data and used only once in final clinical verification. The primary acceptance criterion for this test was 80% agreement between neural-network assessment at its default sensitivity level and the cardiologist reader.

To test automatic cardiac image denoising, 209 sample image series collected from prior versions of Vista OS were assessed along with paired image series that were denoised using default parameters. Among image series assessed, 79% were collected from male

patients, 67% from 1.5 Tesla scanners, and 67% were scanned using GE scanners. Patient ages ranged from 25 to 85 years. Test data was segregated from training and tuning data and used only once in final clinical verification. The primary acceptance criterion for this test was that the denoising should not detract from diagnostic accuracy in all cases, and that the diagnostic quality of the denoised data be judged superior to its paired non-denoised series in more than 80% of test cases.

To test automatic brain localizer prescriptions, 323 sample image localizations were assessed across all provided localizer orientations. Among images assessed, 26% were collected from male patients, 95% from 1.5 Tesla scanners, and 86% were scanned using GE scanners. Patient ages ranged from 30 to 88 years. Test data was segregated from training and tuning data and used only once in final clinical verification. Acceptance criteria for this test included mean error in plane angulation of less than 3 degrees with standard deviation less than 5 degrees, and a mean plane position error less than 5 mm with standard deviation less than 15 mm.

To test automatic prostate localizer prescriptions, 329 sample image localizations were assessed across all provided localizer orientations. Among images assessed, 100% were collected from male patients, 25% from 1.5 Tesla scanners, and 5% were scanned using GE scanners. Patient ages ranged from 49 to 76 years. Test data was segregated from training and tuning data and used only once in final clinical verification. Acceptance criteria for this test included mean 3D Intersection-over-Union (IoU) metrics of at least 0.65 for each volumetric scan prescription.

To test automatic prediction of velocity-encoding VENC for cine flow studies, 42 sample VENC peak estimates were assessed. Among images assessed, 86% were collected from male patients, 21% from 1.5 Tesla scanners, and 21% were scanned using GE scanners. Patient ages ranged from 37 to 75 years. Test data was segregated from training and tuning data and used only once in final clinical verification. The primary acceptance criterion for this test was that the average velocity error should be less than 10% individually for all vessels and views.

The results of all above clinical verification studies evaluating the performance of Vista OS models have demonstrated that their performance meets or exceeds the specified acceptance criteria for each of the tasks being assessed. In addition, all automations are provided as an additional aid to the trained operator who has the final decision power to accept or reject any suggestion or image enhancement that is provided. Therefore, the clinical performance of Vista OS has been adequately verified to meet the requirements for its intended use and demonstrates 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. Neither device supports software-controlled patient table movements and shifts. Both devices support remote access to and imaging on the specific installation's MRI system.

The submitted Vista OS 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, RTHawk 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. RTHawk 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 OS consists of a collection of default protocols containing a combination of RTHawk 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:

- Automatic detection of motion artifacts in Cine Cartesian SSFP
- Automatic detection of ungateable cardiac waveforms
- New AI-based image denoising applicable to cardiac image acquisitions
- A new Brain Localizer App is provided to automatically localize several standard views in the brain
- A new Prostate Localizer App is provided to automatically localize several standard views in the prostate
- Extended the Cardiac Localizer App to provide automatic localization of additional views
- A new Frequency Scout App is provided to automatically determine the frequency offset that minimizes SSFP banding artifacts in the four-chamber view
- A new Cine Flow Calibration App option performs a high-VENC Cine Flow scan and then automatically determines the optimal VENC setting for subsequent scans
- A new inversion pulse is used in the Cardiac T1 Map App to improve inversion efficiency
- Support for new GE software versions HD16, SV25, and MR30.1
- Compatibility with the newer Ubuntu 24.04 operating system version
- Product name change to "Vista AI Scan" / "Vista OS"

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 K212233:

Attribute	RTHawk 3.0.0, K212233	RTHawk 3.3.0: Subject Device
Device Name	RTHawk, HeartVista Cardiac Package	Vista OS, Vista AI Scan, RTHawk
Indications for Use	RTHawk is an accessory to 1.5T and 3.0T whole-body magnetic resonance diagnostic devices (MRDD or MR). It is intended to operate alongside, and in parallel with, the existing MR console to acquire traditional, real-time and accelerated images. The HeartVista Cardiac Package is a collection of RTHawk Apps designed to acquire, reconstruct and display cardiovascular MR (CMR) images. RTHawk produces 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),	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



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	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. RTHawk is intended for use as an accessory to the following MRI systems: Manufacturers: GE Healthcare (GEHC), Siemens Healthineers Field Strengths: 1.5T and 3.0T GE Software Versions: 12, 15, 16, 23, 24, 25, 26 Siemens Software Versions: N4/VE; NX/VA	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
Scanner Compatibility	GE Healthcare, Siemens Healthineers	GE Healthcare, Siemens Healthineers
Magnetic Field Strengths	1.5T, 3.0T	1.5T, 3.0T
Shift/Advance Table	No	No
Imaging Planes	Transverse, Coronal, Sagittal, Oblique, Double Oblique	Transverse, Coronal, Sagittal, Oblique, Double Oblique
Pulse Sequences		
	B0 Mapping	B0 Mapping
		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
	Cine Cartesian SSFP	Cine Cartesian SSFP
	Cine DE Cal	Cine DE Cal
		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
	Gated 3D MRA GRE	Gated 3D MRA GRE
	Gated High-Res GRE	Gated High-Res GRE
	Gated Double-IR FSE	Gated Double-IR FSE
	HART GRE	HART GRE
	HART SSFP	HART SSFP
	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
	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
	Time-Course GRE	Time-Course GRE
	Wait	Wait
Remote Imaging and Support	Yes	Yes
Automated Scan Planning	Yes	Yes



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Conclusion

Based upon verification testing and compliance with voluntary standards, the Company believes that Vista OS and RTHawk are substantially equivalent to the predicate device, and do not raise any new questions of safety or effectiveness.