HeartVista, Inc
% Mr. James J. Rogers
Regulatory & Clinical Affairs and Strategic Quality Assurance
2625 Middlefield Rd., #710
PALO ALTO CA 94306

October 5, 2021.

Re: K212233
Trade/Device Name: RTHawk, HeartVista Cardiac Package
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: September 17, 2021
Received: September 22, 2021

Dear Mr. 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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212233

Device Name
RTHawk, HeartVista Cardiac Package

Indications for Use *(Describe)*
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), 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 Strength: 1.5T and 3.0T
GE Software Versions: 12, 15, 16, 23, 24, 25, 26
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

RTHawk; HeartVista Cardiac Package

510(k) Number: K212233

Submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

1.0 Medical Establishment Registration

Medical Establishment Registration No.: 3011767965

2.0 Contact Information

James Jochen Rogers
FDA Regulatory Affairs, Quality Assurance, and Clinical Studies
T: 724.713.2298
E: jr@heartvista.com

3.0 Establishment Name and Address

HeartVista, Inc.
2625 Middlefield Road, #710
Palo Alto CA 94306

4.0 Submission Date

July 14, 2021

5.0 Device Information

Trade/Proprietary Name: RTHawk, HeartVista Cardiac Package
Common Name: RTHawk, HeartVista Cardiac Package
Model Number(s):

- HeartVista Cardiac Package (HVCP)
- RTHawk

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(s): LNH

6.0 Predicate Device(s)

510(k) #	Device	510(k) Sponsor	510(k) Clearance Date
K183274	RTHawk, HeartVista Cardiac Package	HeartVista	10/18/2019

7.0 Device Description

RTHawk is a software system designed from the ground up to provide a platform for efficient real-time MRI data acquisition, data transfer, image reconstruction, and interactive scan control and display of static and dynamic MR imaging data.

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.

RTHawk is designed to run on a stand-alone linux-based computer workstation, 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 RTHawk Workstation is sourced by the Customer in conformance with HeartVista-provided specifications, and verified prior to installation.

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

The RTHawk application is written to run on top of the Linux operating system, much like application software for word processing, accounting, graphics, etc. Additional software is installed on the MR scanner computer, for receiving communications and control commands from RTHawk, and for directing MRI raw data to RTHawk for image reconstruction, display and processing.

RTHawk is an easy-to-use, yet fully functional, MR Operating System environment. The RTHawk operating system has been designed to provide a platform for the real-time 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.

Conventional MR scanners queue an entire scan ahead of time and provide for little or no modification to a scan already in progress. Conversely, the RTHawk software prepares scan waveforms just as they are needed. RTHawk's efficient management of pulse sequence waveforms and instructions for modifying those pulse sequence waveforms uses the entire scanning interval for preparation of the next sequence. Scan parameters may be manipulated in real time, while providing all checks necessary to assure patient safety. Additional features are provided to automate and facilitate the set of tasks performed during a typical cardiac exam.

RTHawk makes extensive use of spiral image acquisition techniques to maximize scan efficiency. While conventional scans acquire data line-by-line in a Cartesian grid, RTHawk collects data more efficiently in a spiral pattern. Spiral-pattern raw data must be reformatted for correct reconstruction and display, requiring additional computing resources and image correction procedures to reduce image artifacts and distortions, ensuring high-quality reconstructed images.

RTHawk implements the conventional MRI concept of anatomy- and indication-specific Protocols (e.g., ischemia evaluation, valvular evaluation, tissue characterization, etc.). Protocols are pre-set by HeartVista, 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.

The HeartVista Cardiac Package is a collection of RTHawk APPs that enables the performance of a comprehensive cardiovascular MR (CMR) study in a clinically feasible amount of time. These APPs are designed and optimized to acquire, reconstruct, and display CMR images, with features including:

- On-the-fly, sub-second latency adjustment of image acquisition parameters (e.g., scan plane, flip angle, field-of-view, etc.)
- Real-time imaging, enabling less reliance on ECG gating and artifact suppression techniques. Real-time imaging may be used for scan plane localization, instantaneous tracking of patient motion, and clinical user observation of transient events
- Scan automation tools including automatic push-button localization of standard cardiac views, automatic determination of inversion time, automatic detection of artifacts, and automated myocardial segmentation
- High spatial resolution imaging, including single breath-hold, multi-slice high-resolution GRE app offering near total heart coverage

- Free-breathing, multi-slice SSFP and GRE apps that rapidly acquire high-quality images - potentially useful for patients who suffer from arrhythmia or who cannot hold their breath
- Multi-slice dynamic SR GRE app with one heartbeat temporal resolution for time-course imaging.
- Continuous flow quantification

The conventional MRI concept of anatomy- and indication-specific Protocols is implemented within the HeartVista Cardiac Package. APPs within the HeartVista Cardiac Package are organized into basic Protocols pre-set by HeartVista. The clinical user may modify APP parameters from default values within their ranges. These modified APPs may be saved into new or existing user-created Protocols to create unique CMR-indicated protocols tailored to the user's clinical interests.

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 (2010-03)	1st Level Operating Mode
Safety Parameter Display	SAR, dB/dt
Max SAR	< 4W/kg whole-body
Max dB/dt	1st Level Operating Mode

8.0 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), 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 Strength: 1.5T and 3.0T
GE Software Versions: 12, 15, 16, 23, 24, 25, 26
Siemens Software Versions: N4/VE; NX/VA

9.0 Performance Data - Discussion of Non-Clinical Tests

Design controls quality assurance measures during the development of RTHawk 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

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

Reference #	Title
ANSI/AAMI ES60601-1:2005/ (R)2012 +A1+C1 +A2	(Consolidated text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD), Section 14 Programmable Electrical Medical Systems (PEMS)
IEC 60601-2-33:2010 +AMD1:2013 +AMD2:2015 (Ed 3.2)	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis (radiology).
MS1-2008 (R2020)	Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
MS3-2008 (R2020)	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 (2016)	Digital Imaging And Communications In Medicine (DICOM) Set.
ISO 14971:2007 (R2010)	Medical Devices - Application Of Risk Management To Medical Devices

Risk management, compliant with ISO 14971:2007 (R2010) identified hazards, sequences of events, and resultant harms; developed, implemented, and tested risk-controlling mitigations; and evaluated residual risks.

10.0 Technological Characteristics Comparison to Predicate Device and Discussion

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 RTHawk 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 HeartVista Workstation
- Analysis - contains the image post-processing tools
- Application - HeartVista 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 ef cient processing of raw data to generate MR images via a exible, pipelined topology
- Scan Control - responsible for the real-time network transfer of controlling orders for APPs, APPs parameters modi cations, 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. The HeartVista Cardiac Package is a collection of RTHawk Apps designed to acquire, reconstruct and display cardiovascular MR (CMR) images, and functions and features of those Apps are substantially unchanged from the predicate device.

In this version of the HeartVista Cardiac Package, notable changes include:

- Additional compatibility with Siemens Healthineers MRI scanners with software revisions N4/VE and NX/VA
- Additional views and volumes can be automatically prescribed, including horizontal 3-chamber, vertical 4-chamber, aortic valve, aortic arch, shimming ROI, and 4d flow volume
- The ability to automatically register T1 maps, T2 maps, and Time-Course studies acquired on the short axis
- Coil profile correction can be optionally applied for selected Apps
- Images may optionally be displayed with a pseudocolor colormap
- Default trigger delays are computed based upon patient heart rate and localizer data
- A new user interface is provided for viewing and modifying results of the automatic localizer
- A new tool is provided to allow creation of a patient report
- For the FB DE SSFP App, new options are provided to disable the inversion preparation and to enable additional spin-echo T2 preparation
- A new Wait App is provided, which performs no imaging but allows automatic scanning to pause until a certain condition is met (e.g., a specified time has elapsed since a specified prior scan)
- A tool is provided to automatically select a mid-septal ROI for determining T1 from short-axis images

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 K183274, RTHawk, or HeartVista Cardiac Package:

Attribute	Predicate Device RTHawk 2.5.1, K183274 HeartVista Cardiac Package	Modified Device RTHawk 3.0.0 HeartVista Cardiac Package
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), 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: Manufacturer: GE Healthcare (GEHC) Field Strength: 1.5T and 3.0T	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), 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 Strength: 1.5T and 3.0T

	Scanner Software Versions: 12, 15, 16, 23, 24, 25, 26	GE Software Versions: 12, 15, 16, 23, 24, 25, 26 Siemens Software Versions: N4/VE; NX/VA
Scanner Compatibility	GE Healthcare	GE Healthcare, Siemens Healthineers
Magnetic Field Strength(s)	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
	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 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
	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
	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
Remote Scanning and Support	Yes	Yes
Automated Scan Planning	Yes	Yes

11.0 Conclusions

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