DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 30, 2016

HeartVista, Inc.
James Rogers
FDA Regulatory Affairs, Quality Assurance and Clinical Studies
4984 El Camino Real, Suite 102
Los Altos, California 94022

Re: K153740
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: May 25, 2016
Received: May 31, 2016

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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153740

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:

Manufacturer: GE Healthcare (GEHC)
Field Strength: 1.5T and 3.0T
Scanner Software Versions: 15, 16, 23, 24, 25

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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HEARTVISTA

Section 5: 510(k) Summary

HEARTVISTA

510(k) Summary
RTHawk, HeartVista Cardiac Package
510(k) Number: K153740

Submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

1.0 Medical Establishment Registration

Medical Establishment Registration No.: 3011767965

2.0 Contact Information

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3.0 Establishment Name and Address

HeartVista, Inc.
4984 El Camino Real, Suite 102
Los Altos, CA 94022

4.0 Submission Date

December 21, 2015, May 25, 2016, and June 28, 2016

5.0 Device Information

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

- RTHawk
- HeartVista Cardiac Package

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
K142997	RTHawk 1.0.1	HeartVista	12/17/2014

7.0 Device Description

RTHawk is a software platform intended for the efficient real-time MRI data acquisition, data transfer, image reconstruction, and interactive scan control and display of static and dynamic MR imaging data.

As an accessory to clinical 1.5T and 3.0T MR systems, RTHawk operates 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, with color monitor, keyboard and mouse. A private ethernet network connects the workstation to the MR scanner computer. When not in use, the workstation may be disconnected from the MR scanner with no detrimental, residual impact upon MR scanner function, operation, or throughput.

RTHawk is a linux operating system-level software application that is intended to control the MR scanner, acquiring high quality, real-time MRI image data and performing post-processing. The RTHawk software includes optimized image acquisition applications, a pipelined raw data image reconstruction engine, a rich graphical user interface for interactive scan control, real-time adjustment of pulse sequence parameters, and display of reconstructed images, and drivers and protocols for communications with, and control of, the OEM MR scanner console.

RTHawk Apps (Applications) are comprised 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
- 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 in the table below:

Safety Parameter	Safety Level
Magnet 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:

Manufacturer: GE Healthcare (GEHC)
Field Strength: 1.5T and 3.0T
Scanner Software Versions: 15, 16, 23, 24, 25

9.0 Technological Characteristics Comparison to Predicate Device

The structure of the RTHawk software is identical to the predicate device, and is comprised of the following functional modules:

- 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 efficient processing of raw data to generate MR images via a flexible, pipelined topology
- Scan Control - responsible for the real-time 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 iterface, including APP selection, controls to modify APP parameters, image display, graphical slice prescription, and image review, save, and export.

The predicate device was described as the "HeartVista Workstation with the RTHawk application software." With the current release of RTHawk software, the workstation is specified and validated by HeartVista, and procured by the end-user.

As with the predicate device, RTHawk Apps (Applications) are comprised 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. For safety, the RTHawk software is enhanced for display of worst-cast B1 RMS that the APP can potentially reach while scanning, in addition to already-displayed worst-case SAR, dB/dt.

As a refinement and specialization of the predicate device RTHawk software, the HeartVista Cardiac Package is collection of RTHawk APPs that enables the performance of a comprehensive cardiovascular MR (CMR) study in a clinically feasible amount of time.

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 table below summarizes a comparison of the revised technological characteristics to the predicate device:

Attribute	RTHawk, K142997	***RTHawk, K153740 Modified Device***
Indications for Use	The HeartVista Workstation with RTHawk application software is an accessory to 1.5T and 3.0T whole-body magnetic resonance diagnostic devices (MRDD or MR). The HeartVista Workstation with the RTHawk application software is intended to operate alongside, and in parallel with, the existing MR console to acquire real-time and accelerated images. The HeartVista Workstation with the RTHawk application software is indicated for Cardiovascular MR (CMR) applications. The HeartVista Workstation with the RTHawk application software 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 re ect 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. The HeartVista Workstation with the RTHawk application software is intended for use as an accessory to the following OEM, MRI system, and software release versions: * GE Healthcare (GEHC) Signa HDxt 1.5T, 3.0T. Software versions 15 and 16 * GE Healthcare (GEHC) DVMR 1.5T, 3.0T. Software version 24	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 Scanner Software Versions: 15, 16, 23, 24, 25

Attribute	RTHawk, K142997	***RTHawk, K153740 Modified Device***
Magnetic Field Strength(s)	1.5T 3.0T	1.5T 3.0T
RF Coils	Up to 32-channel Head, Body, Surface, Phased Array. Supports all coils that are currently available on the MRI console	Up to 32-channel Head, Body, Surface, Phased Array. Supports all coils that are currently available on the MRI console
Shift/Advance Table	No	No
Imaging Planes	Transverse, Coronal, Sagittal, Oblique, Double Oblique	Transverse, Coronal, Sagittal, Oblique, Double Oblique
Pulse sequences		
	Cine Cartesian SSFP	Cine Cartesian SSFP
	Cine Spiral SSFP	Cine Spiral SSFP
	Gated High-Res GRE	Gated High-Res GRE
	Gated Double-IR FSE	Gated Double-IR FSE
	Gated Multi-Slice Dyn SR	Time Course GRE (renamed)
	Gated IR GRE Cal	FB DE GRE Cal (renamed)
		Cine DE Cal
		Multi-Slice DE GRE
		FB DE SSFP
		Cardiac T1 Map
	Gated 3D IR GRE	Single-BH 3D DE GRE (renamed)
	Real-Time Loc GRE	Real-Time Loc GRE
	Real-Time Loc SSFP	Real-Time Loc SSFP
	Real-Time Color PC	Real-Time Color PC
	FB Multi-Slice GRE	FB Multi-Slice GRE
		HART GRE
	FB Multi-Slice SSFP	FB Multi-Slice SSFP
		HART SSFP
		Gated 3D MRA GRE
		Nav 3D DE GRE
		Cardiac T2* Map

10.0 Performance Data

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

RTHawk conforms to 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 +C1 +A2	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 Ed 3.0 (2010-03)	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic (radiology).
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
MS8-2008	Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
NEMA PS3.1 - 3.20 (2011)	Digital Imaging And Communications In Medicine (DICOM) Set.
ISO 14971:2007	Medical devices - Application of risk management to medical devices.

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

SNR and uniformity data were provided for the new pulse sequences introduced in this submission. Bench testing results for safety parameters of SAR, dB/dt, and acoustic noise were compared to results from the predicate device and were consistent with previously reported results.

Clinical images were acquired using RTHawk, and were evaluated directly based upon radiologist expertise and found to be diagnostically useful.

11.0 Conclusions

Based upon verification and validation testing, safety 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.