September 8, 2023

CorVista Health, Inc.
Gabrielle Zaeska
Vice President Regulatory Affairs
7144 13th Place NW, Suite 2200
Washington, District of Columbia 20012

Re: K232686
Trade/Device Name: CorVista® System
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular machine learning-based notification software
Regulatory Class: Class II
Product Code: QXX, DQK
Dated: September 1, 2023
Received: September 1, 2023

Dear Gabrielle Zaeska:

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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
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)*
K232686

Device Name
CorVista® System

Indications for Use *(Describe)*
The CorVista® System analyzes sensor-acquired physiological signals of patients presenting with cardiovascular symptoms (such as chest pain, dyspnea, fatigue) to indicate the likelihood of significant coronary artery disease. The analysis is presented for interpretation by healthcare providers in conjunction with their clinical judgment, the patient's signs, symptoms, and clinical history as an aid in diagnosis.

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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Summary of 510(k)

CorVista Health, Inc. [510(k) Number - K232686]

This 510(k) Summary is in conformance with 21 CFR 807.92

Submitter: CorVista Health, Inc. ("CorVista Health")
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Date Prepared: 1 September 2023

Trade Name: CorVista® System

Common Name: Cardiovascular machine learning-based notification software

Classification: Class II

Regulation Number: 21 CFR 870.2380

Classification Panel: Cardiovascular

Product Code: QXX

Subsequent Product Code: DQK

Predicate Device:

	Predicate
Trade / Device Name	Viz HCM
510(k) Submitter / Holder	Viz.ai, Inc.
510(k) Number	DEN230003
Regulation Number	21 CFR 870.2380
Classification Panel	Cardiovascular
Product Code	QXO

The predicate device has not been subject to a design-related recall.

Device Description
The CorVista® System is a non-invasive medical device system comprised of several hardware and software components that are designed to work together to allow a physician to evaluate the patient for the presence of cardiac disease, or cardiac disease indicators, using a static detection algorithm.

The CorVista System has a modular design, where disease-specific "Add-On Modules" will integrate with a single platform, the CorVista Base System, to realize its intended use. The CorVista Base System is a combination of hardware, firmware, and software components with the functionality to acquire, transmit, store, and analyze data, and to generate a report for display in a secure web-based portal. The architecture of the CorVista Base system allows for integration with indication-specific "Add-Ons" which perform data analysis using a machine learned detection algorithm to indicate the likelihood of specific diseases at point of care. The CAD Add-On indicates the likelihood of significant Coronary Artery Disease (CAD). The analysis is presented for interpretation by healthcare providers in conjunction with their clinical judgment, the patient's signs, symptoms, and clinical history as an aid in diagnosis.

Indications for Use
The CorVista® System analyzes sensor-acquired physiological signals of patients presenting with cardiovascular symptoms (such as chest pain, dyspnea, fatigue) to indicate the likelihood of significant coronary artery disease. The analysis is presented for interpretation by healthcare providers in conjunction with their clinical judgment, the patient's signs, symptoms, and clinical history as an aid in diagnosis.

Substantial Equivalence
The CorVista System is substantially equivalent to its predicate device, Viz HCM (DEN230003).

The table below provides a detailed comparison of the CorVista System to the predicate device.

Table 1. Detailed Comparison of the Subject and Predicate Device

Characteristic	Subject Device	Chosen Predicate Device with Justification	Comparison
Intended Use	The CorVista® System is intended to non-invasively analyze physiological signals using machine learning techniques to indicate the likelihood of a cardiovascular disease or condition	Viz HCM is intended to non-invasively analyze physiological signals using machine learning techniques to suggest the likelihood of a cardiovascular disease or condition	Same
Indications for Use	The CorVista® System analyzes sensor-acquired physiological signals of patients presenting with cardiovascular symptoms (such as chest pain, dyspnea, fatigue) to indicate the likelihood of significant coronary artery disease. The analysis is presented for interpretation by healthcare providers in conjunction with their clinical judgment, the patient's signs, symptoms, and clinical history as an aid in diagnosis.	Viz HCM is intended to be used in parallel to the standard of care to analyze recordings of 12-lead ECG made on compatible ECG devices. Viz HCM is capable of analyzing the ECG, detecting signs associated with hypertrophic cardiomyopathy (HCM), and allowing the user to view the ECG and analysis results. Viz HCM is indicated for use on 12-lead ECG recordings collected from patients 18 years of age or older. Viz HCM is not intended for use on patients with implanted pacemakers. Viz HCM is limited to analysis of ECG data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. Viz HCM identifies patients for further HCM follow-up and does not replace the current	Different - This difference does not change the intended use of the device. The safety and effectiveness of the CorVista System in its intended use population has been confirmed through testing. Any differences in the indications for use do not affect the safety and effectiveness of the CorVista System and have been addressed through clinical and bench testing and supported by general and special controls.

Characteristic	Subject Device	Chosen Predicate Device with Justification	Comparison
		standard of care methods for diagnosis of HCM. The results of the device are not intended to rule-out HCM follow-up.	
Product Codes	(primary) QXX (21 CFR 870.2380) (subsequent product code) DQK (21 CFR 870.1425)	(primary predicate) QXO (21 CFR 870.2380) (reference predicates) DQK (21 CFR 870.1425)	Different – codes reflect the disease state detected and hardware components. This difference does not change the intended use of the device
Operation Mode	Spot-check	Viz HCM (DEN230003) Spot-check	Same
Motion	Non-motion	HemoSphere Advanced Monitoring Platform, HemoSphere ClearSight Module (K201446) and Workmate Claris™ System v1.2 (K210392) Both secondary predicates are intended for non-motion.	Same
Patient Population	Adult patients presenting with cardiovascular symptoms	Viz HCM (DEN230003) Adult patients	Different - This difference does not change the intended use of the device. The safety and effectiveness of the CorVista System in its intended use population has been confirmed through testing.

Characteristic	Subject Device	Chosen Predicate Device with Justification	Comparison
Environment of Use	Professional healthcare environment (i.e., local physician offices, clinics and hospital settings) with cellular or Wifi	Viz HCM (DEN230003) Hospital and pre-hospital settings	Same
Prescription vs. Off-the-Shelf	Prescription	Viz HCM (DEN230003) Prescription	Same
Technological Characteristics			
Algorithm	Machine learning-based algorithm	Viz HCM (DEN230003) Machine learning-based algorithm	Same
Algorithm Calculation and Output	Likelihood of significant CAD derived from calculated VCG and PPG features and patient demographics.	Viz HCM (DEN230003) Presence of signs of HCM derived from ECG signal.	Different – The output of the CorVista System provides users with the likelihood of significant CAD for a given patient. The primary predicate indicates the presence of signs of HCM. These signs are equivalent in concept to the calculated features that are used as the inputs to the CorVista machine-learning process and resultant algorithm. Both devices process signals to provide information to users on cardiovascular disease and as such the intended use is not impacted by this difference. The safety and effectiveness of the CorVista System has been confirmed through testing.

Characteristic	Subject Device	Chosen Predicate Device with Justification	Comparison
Ground Truth for Model Training and Validation	Guideline-driven ground truth via invasive catheterization or core-lab adjudicated CTA	Viz HCM (DEN230003) Cardiologist-adjudicated signs of a disease from ECG waveform	Different – The validation of the two devices differs in the level of ground truth that is used to validate performance. The CorVista System has been validated using the patient's disease state as ground truth, while the predicate device utilizes the presence of signs that suggest disease. This difference does not impact the shared general intended use of providing information on cardiovascular status. The safety and effectiveness of the CorVista System has been confirmed through testing.
Measured Physiological Parameters	Synchronously acquired cardiac electrical signals (acquired in orthogonal axes via VCG) and hemodynamic signals (acquired via photoplethysmography (PPG))	HemoSphere Advanced Monitoring Platform, HemoSphere ClearSight Module (K201446) and Workmate Claris™ System v1.2 (K210392) K210392: Oximetry, heart rate, and additional cardiovascular parameters (e.g., blood pressure, oxygen delivery, etc.) K201446: Electrocardiograph and intracardiac electrical signals	Same – The measured physiological parameters of the CorVista System are a subset of those measured by the secondary predicate devices. The safety and effectiveness of the CorVista System has been confirmed through testing.

Characteristic	Subject Device	Chosen Predicate Device with Justification	Comparison
Data Displayed	Likelihood of significant Coronary Artery Disease (CAD)	Viz HCM (DEN230003) Notification Flag for patients who require further HCM follow-up	Different - Display of the likelihood of disease is of superior diagnostic value compared to a notification flag used in the predicate device, therefore the safety and effectiveness is non-inferior compared to the predicate. The clinical performance of the CorVista System for the intended disease and output has been confirmed through testing.
Application Site	Trunk & Digits	HemoSphere Advanced Monitoring Platform, HemoSphere ClearSight Module (K201446) and Workmate Claris™ System v1.2 (K210392) The secondary predicates have application sites including the Trunk (K210392) and Digits (K201446).	Same – The CorVista System utilizes a subset of the application sites utilized by the secondary predicate devices.
Data Output	Tablet easy-to-read display (LCD), Mobile App, and Web App	Viz HCM (DEN230003) Mobile app	Different - This difference does not change the intended use of the device. The safety and effectiveness of the CorVista System has been confirmed through testing.

Characteristic	Subject Device	Chosen Predicate Device with Justification	Comparison
Hardware	Seven-Channel Lead Set, PPG Sensor, Capture Device (Tablet)	HemoSphere Advanced Monitoring Platform, HemoSphere ClearSight Module (K201446) and Workmate Claris™ System v1.2 (K210392) The secondary predicates utilize lead sets, oximeter cables, computer systems, etc.	Different - This difference does not change the intended use of the device. The safety and effectiveness of the CorVista System has been confirmed through testing.
Software	CorVista Health Proprietary Algorithm, CorVista Health Proprietary Application	Viz HCM (DEN230003) Viz.ai Proprietary Algorithm, Viz.ai Proprietary Application	Different - This difference does not change the intended use of the device. The safety and effectiveness of the CorVista System has been confirmed through testing.
Physical			
Degree of Protection Against Electric Shock	Type CF – Applied Part	HemoSphere Advanced Monitoring Platform, HemoSphere ClearSight Module (K201446) and Workmate Claris™ System v1.2 (K210392) Type BF and CF Applied Parts (K201446) Type CF – Applied Part (K210392)	Same – The degree of protection against electrical shock is the same as the secondary predicate devices and is appropriate for the intended use environment. The safety and effectiveness of the CorVista System has been confirmed through testing.

Characteristic	Subject Device	Chosen Predicate Device with Justification	Comparison
Functional and Safety Testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-25 IEC 80601-2-61 IEC 60259 IEC 62133 AIM 7351731 ANSI IEEE C63.27 FCC 47CFR Part 15 Subpart C	HemoSphere Advanced Monitoring Platform, HemoSphere ClearSight Module (K201446) and Workmate Claris™ System v1.2 (K210392) K201446: IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-2-34 IEC 60601-2-57 IEC 60601-2-49 IEC 80601-2-49 Wireless Co-existence K210392: IEC 60601-1 IEC 60601-1-2	Different - This difference does not change the intended use of the device. All devices completed Functional and Safety testing pursuant to their design and intended use. The safety and effectiveness of the CorVista System has been confirmed through testing.
Biocompatibility	ISO 10993 Surface contact Skin Limited duration (<24 hours)	HemoSphere Advanced Monitoring Platform, HemoSphere ClearSight Module (K201446) and Workmate Claris™ System v1.2 (K210392) K201446: ISO 10993 (via predicates) K210392: Connected devices completed biocompatibility	Different - This difference does not change the intended use of the device. All devices completed biocompatibility testing pursuant to their level of patient contact. The safety and effectiveness of the CorVista System has been confirmed through testing.

Summary of Non-Clinical Testing

As part of the product development process and risk assessment, a series of non-clinical verification/validation testing and supplemental studies were conducted on both the hardware and software features of the CorVista System to ensure the device operates as intended. As summarized below, all the studies demonstrated acceptable performance to the protocols tested.

- Software Verification and Validation: The CorVista Base System and CAD Add-On Module underwent verification and validation testing to demonstrate the software operates and performs according to written and pre-approved specifications. Results of the CorVista Base System and CAD Add-On Module verification and validation testing demonstrate acceptance criteria were met.

- Performance Bench Testing: A series of standard bench testing has been performed on the CorVista Base System including battery lifecycle, signal quality, wireless coexistence, label integrity, and other functional verification. All studies demonstrated acceptance criteria were met.

- Electrical & EMC Safety Testing: Electrical and EMC safety testing has been performed on the CorVista Base System. All studies demonstrated acceptance criteria were met. All elements of the CorVista System were determined to meet acceptable performance to the following standards:
    - IEC 60601-1
    - IEC 60601-1-2
    - IEC 60601-2-25
    - IEC 80601-2-61
    - IEC 60259
    - IEC 62133
    - EC53:2013
    - AIM 7351731
    - ANSI IEEE C63.27
    - FCC 47CFR Part 15 Subpart C

- Biocompatibility: CorVista Health conducted biocompatibility testing in accordance with FDA's Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" and ISO 10993-1:2018. The following biocompatibility testing was successfully completed on the CorVista Capture™ device's patient contacting materials:
    - Cytotoxicity – MEM Elution Testing per ISO 10993-5:2009, *Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity*
    - Maximization Testing for Delayed-Type Hypersensitivity in Hartley Guinea Pigs per ISO 10993-10:2010, *Biological Evaluation of Medical Devices – Tests for Irritation and Skin Sensitization*
    - Intracutaneous (Intradermal) Reactivity Testing in New Zealand White Rabbits per ISO 10993-10:2010, *Biological Evaluation of Medical Devices – Tests for Irritation and Skin Sensitization*

- Human Factors / Usability: CorVista Health conducted Human Factors / Usability testing in accordance with FDA's Guidance "Applying Human Factors and Usability Engineering to Medical Devices." Human Factors / Usability Testing was conducted in two different studies to cover the CorVista System and CAD Add-On Module.

- Shelf Life / Cleaning Validation: CorVista Health conducted studies to support the shelf life and cleaning of the CorVista System.
    - A cleaning validation study of the CorVista System was conducted utilizing FDA's Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," AAMI TIR 12: 2020, AAMI TIR 30: 2011, ASTM F3208-20, and ASTM F3293-18. Based on the results of this validation, the CorVista Base System can be cleaned effectively following the Instructions for Use.
    - An accelerated aging study was conducted in accordance with ASTM F1980 to simulate a 2-year shelf life. Test results demonstrated that the device is safe and effective for use throughout a 2-year use life.

Summary of Clinical Testing

The performance of the CorVista® System to indicate the likelihood of significant coronary artery disease (CAD) was evaluated through subgroups enrolled in a prospective, multicenter, non-randomized, repository study. The study was designed to collect and store acquired physiological signals paired with subject meta-data, including clinical outcomes data from subjects within the intended use population. The study included IRB approved clinical protocols with informed consent for each patient. All subjects were consecutively and prospectively enrolled and met the established inclusion/exclusion criteria.

Male and female study subjects (N=1,816) were enrolled into two groups based on their reference standard (invasive coronary angiography (ICA) and Computed Tomography Angiography (CTA)). These subjects were divided into populations A and B for Sensitivity and Specificity testing:

- Population A (found to be positive for significant CAD+): Used for Sensitivity Testing.
- Population B (subjects determined to be negative for significant CAD-): Used for Specificity Testing.

Sensor-acquired physiological signals were collected from the subjects using the CorVista Capture™ device based on the scheduling of their diagnostic imaging procedure. To assess device performance in the intended use population, the actual CAD classification (CAD+ or CAD-) of each subject (as determined by their reference procedure) was compared to the algorithm prediction results derived from the CorVista System with CAD Add-On Module.

The validation population (A and B) used for performance testing included symptomatic subjects with a range of cardiovascular symptoms and risks factors which prompted the use of ICA and CTA for CAD evaluation. The diagnostic performance of the CorVista System in this broad

population was demonstrated to be 88% sensitivity and 51% specificity, with a 0.80 AUC-ROC. These results are comparable to the rule out performance of coronary computed tomography angiography (CCTA). The CorVista System is designed to be used in conjunction with the healthcare provider's clinical judgment, the patient's signs, symptoms, and clinical history as an aid in diagnosis. Please refer to the Instructions for Use for further information.

CVH further conducted an evaluation of repeatability and reproducibility of the CAD Add-On output (i.e., CAD Score) using subjects prospectively enrolled in the IDENTIFY study. For repeatability, subjects had 5 signals collected by the same study coordinator according to the Instructions for Use. For reproducibility, subjects had 3 signals collected, with each signal being collected by a different study coordinator. The resulting statistics demonstrate that the CorVista System produces CAD score results that are both repeatable and reproducible.

Substantial Equivalence Conclusion

The CorVista System has an identical intended use to the legally marketed predicate device (DEN230003). Differences between the CorVista System and the predicate device (DEN230003) do not raise new questions of safety or effectiveness. Based on the clinical testing, non-clinical performance and safety testing of the CorVista System, the CorVista System is substantially equivalent to the legally marketed predicate device (DEN230003).