Analytics for Life, Inc.
Gabrielle Zaeska
Vice President, Regulatory Affairs and Quality
First Canadian Place
100 King Street West, Suite 5600
Toronto, ON M5X 1C9
Canada

Re: K233666
Trade/Device Name: CorVista System with PH Add-On
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular Machine Learning-Based Notification Software
Regulatory Class: Class II
Product Code: SAT
Dated: November 15, 2023
Received: March 5, 2024

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 (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.

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,

for Robert T. Kazmierski -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233666

Device Name

CorVista System with PH Add-On

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 provide a binary output indicating the likelihood of elevated mean pulmonary arterial pressure (mPAP), an indicator of pulmonary hypertension. 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)

Analytics for Life, Inc. [510(k) Number - K233666]

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

Submitter: Analytics for Life, Inc.
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Date Prepared: 15 November 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: SAT

Predicate Device:

	Predicate
Trade / Device Name	CorVista® System
510(k) Submitter / Holder	Analytics for Life, Inc. (formerly CorVista Health, Inc.)
510(k) Number	K232686
Regulation Number	21 CFR 870.2380
Classification Panel	Cardiovascular
Product Code	QXX

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 PH Add-On indicates the likelihood of elevated mean pulmonary arterial pressure (mPAP), an indicator of pulmonary hypertension. 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 provide a binary output indicating the likelihood of elevated mean pulmonary arterial pressure (mPAP), an indicator of pulmonary hypertension. 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, CorVista System with CAD Add-On (K232686).

The table below provides a detailed comparison of the CorVista System (with PH Add-On) to the predicate device.

Table 1. Detailed Comparison of the Subject and Predicate Device

Characteristic	Subject Device	Predicate Device	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	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	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 provide a binary output indicating the likelihood of elevated mean pulmonary arterial pressure (mPAP), an indicator of pulmonary hypertension. 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.	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.	Different - This difference in specific disease state indicated does not change the intended use of the device. Any differences in the indications for use do not affect the safety and effectiveness of the CorVista System with PH Add-On and have been addressed through clinical and bench testing and supported by general and special controls.
Product Codes	(primary) SAT (21 CFR 870.2380)	(primary) QXX (21 CFR 870.2380)	Different – primary product codes reflect the disease state detected. This difference does not change the intended use of the device.
Operation Mode	Spot-check	Spot-check	Same

Characteristic	Subject Device	Predicate Device	Comparison
Motion	Non-motion	Non-motion	Same
Patient Population	Adult patients presenting with cardiovascular symptoms	Adult patients presenting with cardiovascular symptoms	Same
Environment of Use	Professional healthcare environment (i.e., local physician offices, clinics and hospital settings) with cellular or Wifi	Professional healthcare environment (i.e., local physician offices, clinics and hospital settings) with cellular or Wifi	Same
Prescription vs. Off-the-Shelf	Prescription	Prescription	Same
Technological Characteristics			
Algorithm	Machine learning-based algorithm	Machine learning-based algorithm	Same
Algorithm Calculation and Output	Likelihood of elevated mPAP derived from calculated VCG and PPG features and patient demographics.	Likelihood of significant CAD derived from calculated VCG and PPG features and patient demographics.	Similar – both algorithms calculate and output the likelihood of a cardiovascular disease state derived from calculated VCG and PPG features and patient demographics.
Ground Truth for Model Training and Validation	Guideline-driven ground truth via invasive catheterization or core-lab adjudicated TTE	Guideline-driven ground truth via invasive catheterization or core-lab adjudicated CTA	Same– The validation of the two devices both use invasive catheterization to determine ground truth positive reference subjects, and core-lab adjudicated non-invasive imaging modalities to determine reference negative subjects. The safety and effectiveness of the CorVista System with PH Add-On has been confirmed through validation testing.

Characteristic	Subject Device	Predicate Device	Comparison
Measured Physiological Parameters	Synchronously acquired cardiac electrical signals (acquired in orthogonal axes via VCG) and hemodynamic signals (acquired via photoplethysmography (PPG))	Synchronously acquired cardiac electrical signals (acquired in orthogonal axes via VCG) and hemodynamic signals (acquired via photoplethysmography (PPG))	Same, both CorVista System devices use identical acquisition hardware.
Data Displayed	PH report indicating the likelihood of elevated mPAP	CAD report, indicating the likelihood of Coronary Artery Disease (CAD)	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.
Application Site	Trunk & Digits	Trunk & Digits	Same
Data Output	Tablet easy-to-read display (LCD), Mobile App, and Web App	Tablet easy-to-read display (LCD), Mobile App, and Web App	Same

Characteristic	Subject Device	Predicate Device	Comparison
Hardware	Seven-Channel Lead Set, PPG Sensor, Capture Device (Tablet)	Seven-Channel Lead Set, PPG Sensor, Capture Device (Tablet)	Same, both CorVista System devices use identical hardware.
Software	Analytics for Life, Inc. Proprietary Algorithm and Application	CorVista System with CAD Add-On (K232686) Analytics for Life, Inc. Proprietary Algorithm and Application	Same
Physical			
Degree of Protection Against Electric Shock	Type CF – Applied Part	CorVista System with CAD Add-On (K232686) Type CF – Applied Part	Same

Characteristic	Subject Device	Predicate Device	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	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	Same
Biocompatibility	ISO 10993 Surface contact Skin Limited duration (<24 hours)	ISO 10993 Surface contact Skin Limited duration (<24 hours)	Same

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 PH 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 PH 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, packaging 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 Add-On Modules.

- 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 elevated mean pulmonary arterial pressure (mPAP) 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 symptomatic 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=386) were enrolled into two groups based on their reference standard (invasive right heart catheterization (RHC) and core lab adjudicated Transthoracic echocardiogram (TTE)). These subjects were divided into populations A and B for Sensitivity and Specificity testing:

- Population A (elevated mPAP population): Used for Sensitivity Testing.
- Population B (non-elevated mPAP population): 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 known clinical outcome (elevated mPAP, defined as $\geq$ 25mmHg), or non-elevated mPAP (as determined by core lab adjudication of TTE) of each subject was compared to the algorithm prediction results derived from the CorVista System with PH 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 RHC and

TTE for evaluation of their symptoms. The diagnostic performance of the CorVista System in this broad population was demonstrated to be 82% sensitivity and 92% specificity, NPV of >99%, with a 0.95 AUC-ROC. 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.

The performance of the CorVista System was additionally evaluated at a secondary endpoint using a positive population defined using the threshold of mPAP ≥ 21 mmHg. Results of this performance evaluation demonstrated that the PH algorithm at this disease threshold has an AUC-ROC of 0.93, and a sensitivity of 0.78, which passed the pre-specified secondary endpoint.

A4L further conducted an evaluation of repeatability and reproducibility of the PH Add-On output (i.e., PH Score) using subjects prospectively enrolled in the IDENTIFY studies. 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 PH 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 (K232686). Differences between the CorVista System and the predicate device (K232686) do not raise new questions of safety or effectiveness. Based on the clinical testing, non-clinical performance and safety testing of the CorVista System with PH Add-On, the CorVista System is substantially equivalent to the legally marketed predicate device (K232686).