July 26, 2026

Analytics For Life, Inc.
Stephen Davies
Senior Director - Quality
3 Bethesda Metro Center
Suite 700
Bethesda, Maryland 20814

Re: K253576
Trade/Device Name: CorVista System® with PCWP Add-On
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular Machine Learning-Based Notification Software
Regulatory Class: Class II
Product Code: QXO
Dated: June 24, 2026
Received: June 24, 2026

Dear Stephen Davies:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

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

Sincerely,

STEPHEN C. BROWNING -S

CDR 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)*
K253576

Device Name
CorVista® System with PCWP Add-On

Indications for Use *(Describe)*
The CorVista System with PCWP Add-on analyzes sensor-acquired physiological signals of patients presenting with cardiovascular symptoms (such as chest pain, dyspnea, fatigue) with no history of elevated PCWP or prior right heart catheterization. It provides a binary output and indicates the likelihood of elevated PCWP defined as >18 mmHg as measured by right heart catheterization (RHC). 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)

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Contact Details

Analytics for Life, Inc.

3 Bethesda Metro Center Suite 700

Bethesda, MD 20814 United States

Mr. Stephen Davies

sdavies@analytics4life.com

561-452-1058

Device Name

Device Trade Name: CorVista System® with PCWP Add-On

Common Name: Cardiovascular machine learning-based notification software

Classification Name: N/A

Regulation Number: 870.2380

Product Codes: QXO

Legally Marketed Predicate Devices

Predicate #: K233666

Predicate Trade Name: CorVista System with PH Add-on

Product Code: SAT

Device Description Summary

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 is of a modular design where disease-specific "Add-On Modules" will integrate with a singular 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 process 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. The focus of this submission is the PCWP Add-On, which indicates the likelihood of elevated Pulmonary Capillary Wedge Pressure (PCWP). The proposed Indications for Use statement is as follows:

Indication: The CorVista System with PCWP Add-on analyzes sensor-acquired physiological signals of patients presenting with cardiovascular symptoms (such as chest pain, dyspnea, fatigue) with no history of elevated PCWP or prior right heart catheterization. It provides a binary output and indicates the likelihood of elevated PCWP defined as >18 mmHg as measured by right heart catheterization (RHC). 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.

Within the two main components of the CorVista System are multiple hardware and software components that work in combination to facilitate analysis and presentation of the Portal and Add-On report.

Intended Use/Indications for Use

The CorVista System with PCWP Add-on analyzes sensor-acquired physiological signals of patients presenting with cardiovascular symptoms (such as chest pain, dyspnea, fatigue) with no history of elevated PCWP or prior right heart catheterization. It provides a binary output and indicates the likelihood of elevated PCWP defined as >18 mmHg as measured by right heart catheterization (RHC). 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 Comparison

The proposed Indications for Use for the CorVista System with PCWP Add-On and the Indications for Use of the proposed predicate device (K233666) are different. The CorVista System with PH Add-On displays a different disease state likelihood than the proposed predicate device (K233666). The CorVista System with PCWP Add-On displays the patient's likelihood of elevated PCWP, while the proposed predicate device displays the patient's likelihood of elevated mean Pulmonary Arterial Pressure (mPAP). The safety and effectiveness of the CorVista System with these differences has been confirmed through clinical testing. Both the CorVista System with PCWP Add-On and the proposed predicate device (K233666) have identical intended use as

both devices are intended to non-invasively analyze physiological signals using machine learning techniques to output the likelihood of a cardiovascular disease or condition.

Technological Comparison

The CorVista System with PCWP Add-On and predicate (CorVista System with PH Add-On) share the same technocological characteristics. Both devices measure synchronously acquired cardiac electrical signals (acquired in orthogonal axes via VCG) and hemodynamic signals (acquired via photoplethysmography (PPG)). These measurements are recorded using identical acquisition hardware with data displayed via Tablet easy-to-read display (LCD), Mobile App, and Web App. Both Add-Ons utilize a Machine learning-based algorithm to output a likelihood of a cardiovascular disease state.

For both Add-Ons, the CorVista System provides a unique patient report with the same user output presentation details for every patient upon which it is used.

Predetermined Change Control Plan

Analytics for Life, Inc. has submitted a Predetermined Change Control Plan (PCCP) applicable exclusively to the CorVista System with PCWP Add-On. The PCCP describes one specific, manually implemented, post-clearance modification: the addition of patient score-specific positive and negative likelihood ratio information along with a table of Negative Predictive Values and Positive Predictive Values to the CorVista Web Portal and PDF test report. The modification will be implemented as a one-time, centrally deployed update and will apply uniformly to all users of the PCWP Add-On.

Planned Modification

The planned modification will add calculated positive and negative likelihood ratios associated with the patient's existing PCWP score along with a PPV/NPV table for underlying population prevalences. The likelihood ratios will provide supplemental interpretive information that healthcare providers may use to update an estimated pre-test probability to a post-test probability.

The likelihood ratios will be calculated deterministically using the fixed kernel density estimate distributions for the elevated and non-elevated PCWP populations established from the

previously validated clinical dataset to derive the True Positive (TP), False Positive (FP), False Negative (FN) and True Negative (TN) values. At each patient score, the mathematical formulae for the likelihood ratio calculation are as follows:

TP = True Positive

TN = True Negative

FP = False Positive

FN = False Negative

$Sensitivity\ (Sn)$= TP / (TP+FN)

$Specificity(Sp)$ = TN / (TN+FP)

Positive Likelihood Ratio PLR$(s) = \frac{Sn}{1-Sp}$

Negative Likelihood Ratio NLR$(s) = \frac{1-Sn}{Sp}$

To avoid unstable values where there is insufficient density in one of the validation populations, the calculation will be bounded at PCWP scores where there is sufficient density, and scores above or below those bounds will use scores calculated at the boundary closest to the score. The PPV and NPV at various prevalences are fixed information and not calculated dynamically.

Testing Methods, Validation Activities, and Performance Requirements

The modification will be developed and implemented under the manufacturer's established design control, software development, and risk management procedures. Supporting documentation will include updated software requirements and design specifications, risk management documentation, verification and validation protocols and reports, and a human factors study report. The modification will not involve collection of new clinical data, clinical relabeling or adjudication, or training, tuning, fitting, or adaptation of the existing algorithm.

Calculation verification and validation will compare manually calculated likelihood ratio values with the values generated by the implemented Web Portal software for a predefined set of 60 PCWP score values spanning the clinically relevant score range, including values near the decision threshold and in the distribution tails (including values that would be subject to the score bounding described above). For the modification to be eligible for implementation, the

manually calculated and system-generated values must agree for every tested score, with exact agreement to two significant figures and zero permitted deviation. The sample size is intended to provide 95% reliability at a 95% confidence level.

The likelihood ratio displays in the Web Portal and PDF test report will also be verified against the approved software and user-interface requirements. Functional and usability testing will confirm that the values are accurately displayed and that the associated explanatory and helper text is present and clear. Human factors validation will be conducted with healthcare providers to confirm that users can locate, correctly identify, and understand the likelihood ratio information.

The modification will be implemented only after all predefined calculation, display, human factors, risk management, and design control acceptance criteria have been met. If the acceptance criteria are not met and the failure cannot be resolved, the modification will not be implemented under the PCCP.

Communication of Implemented Modification to Users

Following successful completion of the required verification, validation, and risk management activities, the modification will be deployed centrally through the CorVista Web Portal and made available simultaneously to all users of the PCWP Add-On. No software installation or upgrade to individual user devices will be required.

Users will be informed through an updated Instructions for Use and a software version changelog. The updated Instructions for Use will identify where the likelihood ratio information is displayed, explain that the values are calculated using the fixed validation-population kernel density estimate distributions, describe their use in estimating post-test probability, and reinforce that the likelihood ratios are supplemental information to be interpreted together with the other device outputs and the healthcare provider's clinical judgment. No additional user training beyond the updated labeling is planned. Issues associated with the modification will be monitored through the manufacturer's established feedback, complaint-handling, and post-market surveillance processes.

Conclusion Regarding the PCCP

The planned modification does not change the intended use, indications for use, underlying machine-learned algorithm, patient score, decision threshold, or binary PCWP output of the CorVista System with PCWP Add-On. The predefined development controls, numerical acceptance criteria, display verification, human factors validation, risk management activities, and user-communication procedures provide reasonable assurance that the modification may be

implemented in accordance with the authorized PCCP without adversely affecting the safety or effectiveness of the device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Non-Clinical testing supporting S&E of the subject device is supported by a suite of bench testing for the predicate device, the CorVista System with PH Add-On (K233666). Both the subject device (CorVista System with PCWP Add-On) and the predicate device share equivalent hardware comprised of the CorVista Capture. A4L is providing this summary and leveraging all testing conducted and submitted under K233666 in support of this present application.

As noted in the submission summary, Analytics for Life, Inc. has created a new revision of the hardware portion of the device, called Capture 2. This hardware update contains only minor changes from the Capture 1 hardware used to collect clinical data for this submission. No Capture 2 data was used in the performance validation of this submission; it is presented to inform FDA of the current device configuration that Analytics for Life, Inc. intends to go to market with once cleared. The device update was done via letter to file, which can be found attached to this submission as “Letter to File – Capture 2". The principal changes to hardware included a new lead set as well as a new iPad version along with modified case dimensions. The modified lead set conforms to the same performance specifications as the original including conformance to standard including EC53:2013, IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-25. Additionally, Capture 2 completed all required bench testing as the previous device with passing results. Capture 2 bench testing results are included in the ESTAR as evidence of conformance to requirements.

A4L is leveraging bench testing conducted and submitted under K233666 in support of this present application for clinical data captured on Capture 1 software.

The list of testing is as follows:

-Software Verification & Validation

-Bench Testing: Battery Lifecycle, signal quality, wireless coexistence, label integrity, and other functional verification. All studies demonstrated acceptance criteria were met 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:

o IEC 60601-1

o IEC 60601-1-2

o IEC 60601-2-25

o IEC 80601-2-61

o IEC 60259

o IEC 62133

o EC53:2013

o AIM 7351731

o ANSI IEEE C63.27

o FCC 47CFR Part 15 Subpart C

-Biocompatibility:

o Cytotoxicity – MEM Elution Testing per ISO 10993-5:2009, Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity

o 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

o 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

•Shelf Life / Cleaning Validation: A4L conducted studies to support the shelf life and cleaning of the CorVista System.

o 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.

o 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

Package Testing: Updated packaging testing was completed to comply with the requirements of ISTA 3A 2018

Human Factors/Usability Testing: 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 leveraged for the PH and PCWP Add-On Modules

The performance of the CorVista® System to indicate the likelihood of elevated Pulmonary Capillary Wedge Pressure (PCWP) 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=255) 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 PCWP population): Used for Sensitivity Testing.

Population B (non-elevated PCWP 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 PCWP, defined as ≥ 18mmHg), or non-elevated PCWP (as determined by core lab adjudication of TTE) of each subject was compared to the algorithm prediction results derived from the CorVista System with PCWP 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 further evaluation. The diagnostic performance of the CorVista System in this broad population was demonstrated to be 82% sensitivity (95% confidence interval: 74%–89%) and 83% specificity (95% confidence interval: 76%–89%), with an NPV of >99% and a PPV of 13.0%, calculated assuming a population disease prevalence of 3%, and an AUC-ROC of 0.91. 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 PCWP test is designed to identify patients with elevated PCWP within the intended use population, i.e., patients with new onset cardiovascular symptoms. Based on our review of the literature, we estimate that for patients initially presenting with cardiovascular symptoms, less than 1% undergo right heart catheterization (RHC). An even lower percentage (~0.5%) of

patients deemed to be negative for elevated PCWP undergo right heart catheterization since in >99%, the absence of elevated PCWP is adjudicated using noninvasive tests such as transthoracic echocardiography, NT-proBNP and a variety of demographic and laboratory-based risk scores. In our study over 50% of patients referred for RHC also underwent left heart catheterization. Roughly a third were found to have coronary artery disease. Therefore, patients referred for RHC are not a part of our intended use specificity population and were not included in the specificity population used for validation. The PCWP test is not an appropriate test for patients in whom referral for RHC is already anticipated. However, we provide an estimate of the specificity of the PCWP test in patients who were referred for RHC and were negative for significant elevation in PCWP defined as PCWP <= 18 mmHg. Moreover, we also provide the specificity in patients with low-normal PCWP, defined as PCWP <= 10 mmHg along with the associated 95% confidence intervals. In contrast to our intended use population, in whom the specificity of the PCWP test is 83.0%, we found that in the RHC negative population, defined as PCWP <= 18 mmHg, the specificity is 26.3% (0.221, 0.307) and in the subset with PCWP <= 10 mmHg, the specificity is 26.5% (0.208, 0.329). The lower specificity in the high-risk patient subset referred for RHC compared to our validation population is not unexpected given that RHC patients typically have already undergone multiple noninvasive and/or invasive cardiovascular tests, and many have significant coronary artery disease and/or other co-morbidities. Table 1 below shows point estimate and 95% CIs for specific PCWP ranges.

PCWP Range (mmHg)	**Point Estimate (n/N)**	**95% Confidence Intervals**
Specificity where PCWP <= 4	21.4% (6/28)	(0.083, 0.410)
Specificity where PCWP <= 6	29.7% (22/74)	(0.197, 0.415)
Specificity where PCWP <= 8	28.0% (42/150)	(0.210, 0.359)
Specificity where PCWP <= 10	26.5% (58/219)	(0.208, 0.329)
Specificity where PCWP <= 12	27.1% (76/280)	(0.220, 0.328)
Specificity where PCWP <= 14	26.1% (89/341)	(0.215, 0.311)
Specificity where PCWP <= 16	26.4% (102/386)	(0.221, 0.311)
Specificity where PCWP <= 18	26.3% (110/419)	(0.221, 0.307)

Table 1. Device specificity within cumulative PCWP subgroups in the RHC non-elevated PCWP population. Point estimates represent the proportion of subjects correctly classified as PCWP non-elevated (True Negatives / Total Negatives). Confidence intervals calculated using the Wilson score method.

A4L further conducted an evaluation of repeatability and reproducibility of the PCWP Add-On output (i.e., PCWP 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 PCWP score results that are both repeatable and reproducible.

The CorVista System with PCWP Add-On has an identical intended use to the legally marketed predicate device (K233666). Differences between the CorVista System and the predicate device (K233666) 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 PCWP Add-On, the CorVista System is substantially equivalent to the legally marketed predicate device (K233666).