October 6, 2023

Avicena, LLC
℅ Lorry Weaver
Principal Consultant
Qserve Group, US
350 S. Main Street Suite 309
Doylestown, Pennsylvania 18901

Re: K223905
Trade/Device Name: Vivio® LVEDP System
Regulation Number: 21 CFR 870.2200
Regulation Name: Adjunctive Cardiovascular Status Indicator
Regulatory Class: Class II
Product Code: QUO
Dated: January 11, 2023
Received: January 13, 2023

Dear Lorry Weaver:

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.

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,

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
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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)*
K223905

Device Name
Vivio® System

Indications for Use *(Describe)*
The Vivio® System is indicated to non-invasively estimate left ventricular end-diastolic pressure (LVEDP) is above or below 18mmHg. This measurement can aid in the diagnosis of heart failure when used by qualified healthcare professionals as an adjunct alongside other clinically relevant information. For use in adults only.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## Section 5: 510(k) Summary – [21 CFR 807.92]

*807.92(a)(1), (2), (3)*

**Date Prepared:** July 20, 2023

**Submitter's Name:** Avicena, LLC
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**Device Trade Name:** Vivio® System

**Common Name:** Adjunctive cardiovascular status indicator for left ventricular end diastolic pressure (LVEDP)

**Review Panel:** Office of Cardiovascular Devices (OHT2)

**Classification Name:** Adjunctive cardiovascular status indicator

**Regulation No.**: 870.2200

**Classification Code:** QUO

**Predicate Device:** **EchoGo Heart Failure**: 510(k) Number K222463
Classification Code: QUO
Regulation: 870.2200

**Device Description** *807.92(a)(4)*:

The Vivio System consists of an Arm Cuff system (BP cuff electronics, connection tubing), EKG patch, and a software application that runs on an off-the-shelf computer tablet. Data is collected non-invasively at the brachial artery and via a single-lead EKG Patch. An off-the-shelf blood pressure arm cuff is attached to the patient's upper arm as if taking a blood pressure measurement. The Arm Cuff is attached to the blood pressure cuff with the quick connect end connected to the pneumatic pump within the Arm Cuff Electronics Enclosure. Two off-the-shelf electrodes are attached to the snap connections on the bottom of the EKG Patch and then connected on the left side of the patient's chest. Both the pneumatic pump attached to the Arm Cuff and EKG Patch are then powered on by pressing and releasing their respective power buttons. The Vivio App is opened on an off-the shelf computer tablet, and the on-screen prompts are followed to connect the Arm Cuff and the EKG Patch. The user is prompted to enter required patient and user data, initiating a patient recording session. Data from the recording session is processed by a proprietary algorithm and results reported on the computer tablet.

The Vivio System Is designed for use by qualified healthcare professionals.

**Indications for Use** *[Intended Use 807.92(a)(5)]*:

The Vivio® System is indicated to non-invasively estimate left ventricular end-diastolic pressure (LVEDP) is above or below 18mmHg. This measurement can aid in the diagnosis of heart failure when used by qualified healthcare professionals as an adjunct alongside other clinically relevant information. For use in adults only.

**Technological Characteristics** *807.92(a)(6)*:

The Vivio® System ("Vivio") and EchoGo Heart Failure ("EchoGo") have similar technological characteristics both within regulation 870.2200 and product code QUO. The devices are prescription devices based on sensor technology or image data to provide information to an interpreting clinician in detecting heart failure. Each device is intended for adjunctive use with other physical vital sign parameters and patient information and neither device is intended to independently direct therapy.

The technical method described for product code QUO is aligned with both devices which analyze patient data (such as echocardiographic images) and provide an output that indicates likelihood of the presence of heart failure. The Vivio and EchoGo each meet this technical method definition. Vivio analyzes patient waveform data from custom sensor technology placed on the arm and chest of a patient. Vivio analyzes the acquired data to output an estimate of LVEDP to aid a clinician in the process of arriving at a diagnosis of heart failure. EchoGo analyzes patient echocardiographic data and informs the clinician that the acquired data is suggestive of heart failure with preserved ejection fraction. Vivio and EchoGo each interpret non-invasive data to provide a binary outcome in which the status indicator can be represented as normal or abnormal; LVEDP above or below 18 mmHg for the Vivio and the echocardiogram provided as suggestive of heart failure or not suggestive of heart failure for the EchoGo.

Vivio and EchoGo do have some differences that do not raise new issues of safety or efficacy. The method by which the two devices acquire their non-invasive patient data is different. The EchoGo uses echocardiographic images acquired by ultrasound. The Vivio uses pulse and ECG waveform information acquired using custom hardware. This difference in how the patient data is acquired does not present new or different issues related to safety or effectiveness as both devices provide a heart failure status that is adjunct to other clinical parameters. Additionally, the algorithm approach between Vivio and EchoGo is different. EchoGo uses a machine learning process to determine whether the echocardiographic images acquired are suggestive of heart failure. Vivio uses a fixed parameter model to determine whether LVEDP is greater than 18 mmHg.

A summary of similarities and differences are summarized below.

Similar features:

- Adjunctive use alongside clinically relevant information
- Qualitative result - interpret non-invasive data to provide a binary outcome
- Non-invasive sensor technology
- Aid in diagnosis of heart failure
- Use by qualified healthcare professionals

Differing features:

| EchoGo | Vivio System |
|---|---|
| Artificial intelligence (AI) model developed using a convolutional neural network | Algorithm uses a fixed parameter model to predict status indicator |
| Echocardiographic data images from ultrasound DICOM files | Waveform data from custom sensor technology |

**Summary of Non-Clinical Test - Performance and Safety Testing** *807.92(b)(1)*:

Special Controls defined in 870.2200 have been met as provided in the 510(k) submission.

The Vivio System was evaluated and found to meet standards and requirements for biocompatibility, electrical, electromagnetic, and packaging.

Biocompatibility

Biocompatibility testing was conducted on the body contacting materials according to ISO 10993-1 5th edition 2018-08 for transient exposure (< 24 hours per the ISO guideline and typically ≤ 2 hours in the actual clinical application), external communicating device. All testing passed pre-defined acceptance criteria.

Electrical Safety and EMC

Vivio System meets the requirements of the relevant elements of the following electrical safety and EMC standards.

- AAMI ES60601-1:2005 + A1:2012 + A2:2010 + C1:2009 + A2:2021 *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + A1:2012 + A2:2020 + US differences)*
- AAMI HA60601-1-11:2015 + A1:2021 *Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 + A1:2020 + US differences)*
- IEC 60601-2-47:2012 *Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems*
- IEC 80601-2-30:2018 *Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers*
- IEC 60601-1-2:2014 + A1:2020 – *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

- ETSI EN 300 328:2019-07 *Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonized Standard for access to radio spectrum*
- ETSI EN 300 328-1:2001-12 *Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques; Part 1: Technical characteristics and test conditions*
- EN 50566:2017 *Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body.*
- AIM 7351731:ver3 *Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers.*

Packaging

The Vivio System packaging system was tested and meets the requirements according to ASTM D4169-22.

Usability

A usability simulation study was conducted demonstrating that users were able to correctly interpret the LVEDP result (Special Control #3) provided by the Vivio System.

**Summary of Clinical Tests** *807.92(b)(1)*:

Avicena conducted a prospective validation study to characterize the relationship of Avicena's non-invasive Vivio System for the estimation of elevated left ventricular end-diastolic pressure (LVEDP) as compared to gold-standard invasive LVEDP obtained via the Millar Mikro-Cath (Cath Lab Cohort) as well as reference-standard non-invasive echocardiographic indices (Aged Healthy Cohort). An additional non-aged healthy cohort was enrolled without the use of a reference comparator (Non-Aged Healthy Cohort).

A prospective, multi-center clinical study enrolled 195 subjects scheduled for non-emergent left heart catheterization in a cardiac catheterization laboratory (Cath Lab Cohort) across 9 sites. A non-aged Healthy Cohort of 101 subjects were also enrolled at a single site. An additional Aged Healthy Cohort of 40 subjects were additionally enrolled at a single site. Statistical analysis was performed on a subset of validation data that had passed the completeness and quality requirements outlined in the data management plan and procedure.

The primary efficacy objectives for the study were met; sensitivity of 80% (64–91), and specificity of 80% (73–86).

**Conclusion** *807.92(b)(1)*:

The Vivio System and EchoGo Heart Failure 1.0 both fall within regulation 870.2200 and product code QUO. The intended use and key technological characteristics are substantially equivalent, and differences do not raise new or different questions of safety and effectiveness. Both devices provide a measurement of a physical parameter based upon sensor technology as an aid in diagnosis for adjunctive use with other physical vital sign parameters and patient information.

The Vivio System meets the special controls defined in 21 CFR 870.2200. The device conforms to applicable safety standards and clinical performance data validates the intended use. The predicate comparison table and performance testing provided in this 510(k) provide the necessary information to demonstrate the Vivio System is substantially equivalent to the legally marketed predicate device, EchoGo Heart Failure 1.0 cleared under 510(k) K222463.