October 4, 2019

Avicena, LLC
% James West
Principal Consultant
West Device Innovations, LLC
23412 West 46th Street
Shawnee, Kansas 66226

Re: K183710
Trade/Device Name: Vivio System
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 22, 2019
Received: August 27, 2019

Dear James West:

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,

for Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183710

Device Name
Vivio System

Indications for Use *(Describe)*
The Vivio System is indicated for low frequency (<200 Hz) or Bell Mode operation to acquire and transmit heart sound data to the tablet/UI (with Avicena App) for calculation of heart rate and display and playback of heart sounds (audio and visual).

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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Traditional 510(k) Summary for K183710

Summary Date:	02 Oct. 2019
Applicant Name:	Avicena, LLC, 117 East Colorado Blvd, Suite 510 Pasadena CA 91105, Ph: 626.344.9665, Email: info@avicenaheart.com Establishment Registration Number: FDA Registration is pending.
Submission Correspondent:	On behalf of Avicena LLC., the following consultant is assigned the responsibility of submission correspondence: Jim West, Principal Consultant at West Device Innovations, LLC 23412 West 46'th Street, Shawnee, KS 66226, Ph: 913.991.6288, Email: jwest@westdeviceinnovations.com
Trade Name:	Vivio System
Common Name:	Digital Electronic Stethoscope
Description:	The Vivio Unit is an electronic stethoscope containing a membrane, placed on the skin over the carotid artery, that is displaced due to vibrations produced by the arterial pulse waveform and heart sounds associated with the aortic valve opening and closing. An infrared light photo reflector transmits and detects light to/from the membrane and outputs a current relative to the detected light (or membrane movement). Sensor electronics inside the Vivio Unit generate a current to operate the sensor, read the current produced by the sensor and output a voltage relative to the current. Filter electronics condition the sensor signal, process the data and communicate the data to the tablet with the Avicena App. The Vivio Unit is powered by an internal, rechargeable battery.
Classification Regulation, Class & Product Code & Panel:	21 CFR 870.1875(b) Class II Product Code: DQD Panel: Cardiovascular

Intended Use of Device

Product Requirements Document - Avicena Vivio Device	
Indications for Use:	The Vivio System is indicated for low frequency (<200 Hz) or Bell Mode operation to acquire and transmit heart sound data to the tablet/UI (with Avicena App) for calculation of heart rate and display and playback of heart sounds (audio and visual).
Intended Use:	The Vivio System is intended to be used as part of a physical assessment of a patient by healthcare professionals for diagnostic decision support. It may be used for the detection and amplification of sounds from the heart and arteries with the use of selective frequencies. It can be used on any person undergoing a physical assessment.
Intended User:	The Vivio System is intended to be used by Healthcare Providers.
Intended Use Environment:	The Vivio System is intended to be used in a clinical setting such as a hospital, physician's office, or other patient care facility.
Targeted Patient Population:	It can be used on any person undergoing a physical assessment..
Contraindications:	Subjects with a hypersensitive response to even slight pressure over the carotid pulse may faint when the carotid is palpated (carotid sinus hypersensitivity). For this reason, the following are contraindications for the use of the Vivio System: ● Patients with a history of carotid sinus hypersensitivity (fainting in response to touching or positioning the neck) ● Patients with a known history of carotid artery stenosis ● Open skin lesions at the site of examination

Predicate Device(s):	510(k) Number: K083903 Manufacturer: 3M Company Trade Name: 3M Littmann Electronic Stethoscope, Model 3200 Product Code: DQD Classification: 870.1875
Reference Device(s):	510(K) Number: K122129 Manufacturer: AtCor Medical

	Trade Name: SphygmoCor XCEL Product Code: DSK; DXN Classification: Computer, Blood-Pressure; System, Measurement, Blood-Pressure, Non-Invasive

Comparison to Predicate

The Vivio System combines the following features into one product that consists of a physical stethoscope for collection of heart sounds, and software in the form of an app on a tablet to record, playback and visualize the sounds recorded. The Vivio System, Model 1.0 under review and the predicate have similar indications for use. The devices are substantially equivalent. Table 1 below is a summary of the differences between the devices and a commentary regarding the reasons the differences do not introduce additional safety or efficacy concerns.

The proposed device and the predicate device have the same/equivalent intended use, intended user, intended use environment and targeted patient population. The device under consideration uses for a predicate device, the 3M Littmann Model 3200 Electronic Stethoscope (cleared under 510(k) K083903) used in conjunction with the Zargis StethAssist phonocardiogram software. Additionally a reference device is included, the AtCor Medical SphygmoCor XCEL (cleared under 510(k) K122129). It should be noted that phonocardiograms are 510(k) exempt devices per 870.2390. Essentially, the use of the Littmann Model 3200 with StethAssist software is related to heart sounds, heart sound waveforms, and heart rate visualization, and SphygmoCor for arterial pulse waveform visualization which can be used by the clinician as an assessment to indicate adequate system application/placement and is not presented for clinical interpretation.

The Vivio product differs from the predicate in the areas of:

- signal export capability
- replaceable diaphragm
- latex indication label
- category AP Equipment classification labeling
- sharp edges caution statement
- electric warning labeling
- visualization of the arterial pulse waveform for assessing adequate device placement

While the differences listed affect the design and form of the product they do not introduce any safety, performance or efficacy concerns.

Table 1 Differences between Vivio System and Predicate Efficacy/Safety Concerns

	Vivio System (Subject Device) (K183710)	3M Model 3200 with Zargis StethAssist (Predicate Device) (K083903)	Comments on Efficacy/Safety
Information			
Signal Export	No export functionality.	Can export .wav and .zsa files and print a report.	The Vivio System does not allow for long term storage, and as such has no mechanism to export data. This has no impact on safety or efficacy.
Arterial Pulse Waveform	Displays on tablet.	No.	Used as an assessment to indicate adequate system application/placement and is not presented for clinical interpretation.
Design			
Replaceable diaphragm	No, the system is self-contained and not modifiable by the users.	Yes, the diaphragm can be replaced	It is not possible for a user to modify the Vivio Device. While this is a difference between the predicate, it offers no risk to safety or efficacy.
Labeling			
No latex indication	No	Yes	Our product has no latex in its packaging or construction, but we have not added this declaration to our labels.
Arterial Pulse Waveform	Yes	No	The following is included in the Instructions for Use: The arterial pulse waveform is used as an assessment to indicate adequate system application/placement and is not presented for clinical interpretation.
Category AP Equipment	No	Yes	The Vivio System has not been tested for flammable anesthetic mixture with air. It is not intended for use in a surgical environment.
Electric shock warning	Usage is not allowed when device is plugged into wall power. The Vivio	To reduce the risk associated with an electrical shock do not use the stethoscope on	Since the Vivio Unit does not have a removable diaphragm, there is not an equivalent warning. The device additionally

	device will not pair with the tablet when plugged into mains power.	patients without the stethoscope's diaphragm cover in place.	will not function while connected to mains power as an additional safety measure.

Summary of Clinical and Non-Clinical Testing

This submission does not include animal or clinical performance testing.

This submission includes data from bench testing to evaluate the performance of the Avicena Vivio System – Electronic Stethoscope. Testing involved performance and bench testing as well as user and usability testing.

Although there are no specific performance standards for this device, the device was tested for compliance with voluntary standards as outlined in the following table.

Testing to the following standards was conducted per the standards requirements:

- CFR 21CFR820: Part 820 - QUALITY SYSTEM REGULATION,
- IEC 62304:2006 + A1:2015 Medical device software - Software life cycle processes,
- ISO 14971:2012 Medical devices - Application of risk management to medical devices,
- ASTM D4169-16 Performance Testing of Shipping Containers and Systems,
- AAMI ES 60601-1:2005 + A1:2012 + A2:2010 +C1:2009 – Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and U.S. Food and Drug Administration (FDA) Guidance Document for the Use of ISO 10993-1 (issued 06/16/2016)
- IEC 60601-2-27: 2011/(R)2016 Medical electrical equipment - Part 2-27 Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

Conclusions

Avicena believes the proposed Vivio System and its predicate the 3M Littmann Model 3200 Electronic Stethoscope are substantially equivalent in their intended use, intended users, intended use environment and indications for use. They share similar design and technology output characteristics as well as recording the same biological functions. The differences that exist between the devices do not affect the relative safety and/or effectiveness.