January 7, 2020

VivaLNK, Inc.
Quoi Huynh
Vice President of Operations
51 E. Campbell Ave. Suite 160
Campbell, California 95008

Re: K191870
Trade/Device Name: VV330 Continuous ECG Platform, VivaLNK Adhesive Patch
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: December 5, 2019
Received: December 9, 2019

Dear Quoi Huynh:

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 Jessica Paulsen
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191870

Device Name
VV330 Continuous ECG Platform

Indications for Use *(Describe)*
VV330 Continuous ECG Platform is a wireless recording system intended for use by healthcare professionals for record and display of physiological data within healthcare settings or at home. This includes electrocardiogram (ECG), accelerometer data, R-R Interval and heart rate. Data is transmitted wirelessly to a separate location (such as a mobile phone) for storage and display.

The VV330 Continuous ECG Platform can be configured by Authorized Persons to modify or merge or ignore any of the operational alerts, but not to set new alerts related to physiological data.

The device is not intended to be used on critical care patients and is intended to supplement vital signs recording for later viewing by healthcare professionals, not to replace current standards of care. The device is an ambulatory, continuous recording system intended for use on general care patients and on patients who are 18 years of age or older.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5. 510(k) Summary

1. General Information

510(k) Sponsor	VivaLNK, Inc.
Address	51 East Campbell Ave, Suite#160 Campbell, CA 95008
Correspondence Person	Quoi Huynh
Contact Information	Qh@vivaLNK.com 408 205-4202
Date Prepared	July 10th, 2019

2. Subject device:

Proprietary Name	VV330 Continuous ECG Platform
Classification Name	Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulation Number	870.2910
Product Code	DRG
Regulatory Class	II

3. Primary Predicate Device:

Proprietary Name	VitalConnect Platform
Premarket Notification	K132447
Classification Name	Transmitters and Receivers, Physiological Signal, Radiofrequency Detector and alarm, arrhythmia
Regulation Number	870.2910 870.1025
Product Code	DRG, DSI
Regulatory Class	II

4. Secondary Predicate Device:

Proprietary Name	VitalConnect Platform
Premarket Notification	K141167
Classification Name	Transmitters and receivers, physiological signal, radiofrequency

	Detector and alarm, arrhythmia Monitor, physiological, patient (with arrhythmia detection or alarm)
Regulation Number	21 C.F.R. 870.2910 21 C.F.R. 870.1025 21 C.F.R. 870.1025
Product Code	DRG, DSI, MHX
Regulatory Class	II

5. Device Description

The VV330 Continuous ECG Platform is a single-channel, rechargeable, re-usable, ambulatory medical-grade continuous ECG recorder, intended for use by healthcare professionals for record and display of physiological data within healthcare settings or at home.

The device is not intended to be used on critical care patients and is intended to supplement vital signs recording for later viewing by healthcare professionals, not to replace current standards of care. The device is an ambulatory, continuous recording systems intended for use on general care patients and on patients who are 18 years of age or older.

The VV330 Continuous ECG Platform is an ECG acquisition, storage, and transmission devices that utilizes disposable adhesive to maintain contact with the patient's skin and a hydrogel to promote electrical connectivity. The Platform has a re-usable sensor/recorder module allowing collection, storage and transfer of physiological data such as electrocardiogram (ECG), Accelerometer data, R-R Interval (RRI) and Heart Rate (HR). The Platform has a mobile data-display application built from a proprietary Software Library. And it also allows Authorized Persons to build their own applications using the same Software Library.

User's physiological are not transferred to healthcare professionals directly in any way; healthcare professionals can only view the data on the intended device (such as a mobile phone). User may view the physiological data in real time from the smart phone (or similar devices) while it records the data.

The Subject device provides operational alarms such as lead on/off status detection, battery monitoring, Over the Air (OTA) updates, real time clock, and power management. The operational alarms are intended to notify users of any interruption in data and of the overall operation status of the Recorder. The Subject device, being just a Transmitters and Receivers of Physiological Signal, does not provide any alarms based on physiological data setting.

6. Indications for Use

VV330 Continuous ECG Platform is a wireless recording system intended for use by healthcare professionals for record and display of physiological data within healthcare settings or at home. This includes electrocardiogram (ECG), accelerometer data, R-R Interval and heart rate. Data is transmitted wirelessly to a separate location (such as a mobile phone) for storage and display. The VV330 Continuous ECG Platform can be configured by Authorized Persons to modify or merge or ignore any of the operational alerts, but not to set new alerts related to physiological data.

The device is not intended to be used on critical care patients and is intended to supplement vital signs recording for later viewing by healthcare professionals, not to replace current standards of care. The device is an ambulatory, continuous recording system intended for use on general care patients and on patients who are 18 years of age or older.

7. Comparison of Indications for Use and Technological Characteristics with the Primary and Secondary Predicates

Feature/ Function	**Subject device:** VV330 Continuous ECG Platform	**Primary Predicate Device:** VitalConnect Platform (K132447)	**Secondary Predicate Device:** VitalConnect Platform (K141167)
Indications for Use			
Indications for Use	VV330 Continuous ECG Platform is a wireless recording system intended for use by healthcare professionals for record and display of physiological data within healthcare settings or at home. This includes electrocardiogram (ECG), accelerometer data, R-R interval and heart rate. Data is transmitted wirelessly to a separate location (such as a mobile phone) for storage and display. The VV330 Continuous ECG Platform can be configured by Authorized Persons to modify or merge or ignore any of the operational alerts, but not to set new alerts related to physiological data.	The VitalConnect Platform is a wireless monitoring system intended for use by healthcare professionals for unattended surveillance of physiological data within healthcare settings. This includes heart rate, electrocardiography (ECG), heart rate variability, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data is transmitted wirelessly to a central location where it is stored for analysis. The VitalConnect Platform can be configured by Authorized Persons to notify healthcare professionals	The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This includes heart rate, electrocardiography (ECG), heart rate variability (R-R interval), respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data is transmitted wirelessly to a central location where it is stored for analysis. The VitalConnect Platform can be configured by Authorized Persons to notify healthcare professionals when physiological data falls outside selected parameters.

Feature/ Function	Subject device: VV330 Continuous ECG Platform	Primary Predicate Device: VitalConnect Platform (K132447)	Secondary Predicate Device: VitalConnect Platform (K141167)
	The device is not intended to be used on critical care patients and is intended to supplement vital signs recording for later viewing by healthcare professionals, not to replace current standards of care. The device is an ambulatory, continuous recording system intended for use on general care patients and on patients who are 18 years of age or older.	when physiological data falls outside selected parameters. The device is not intended to be used on critical care patients and is intended to supplement vital signs monitoring by healthcare professionals, not to replace current standards of care. The device is intended for use on general care patients and on patients who are 18 years of age or older. It is not intended for home use.	The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform is intended for use by healthcare professionals as an aid to diagnosis and treatment. It is not intended for use on critical care patients.
Regulations and Product Code(s)	21 CFR 870.2910, DRG- Transmitters and Receivers, Physiological Signal, Radiofrequency	21 CFR 870.2910, DRG- Transmitters and Receivers, Physiological Signal, Radiofrequency 21 CFR 870.1025, DSI- Detector and alarm, arrhythmia	21 CFR 870.2910, DRG- Transmitters and Receivers, Physiological Signal, Radiofrequency 21 CFR 870.1025, DSI- Detector and alarm, arrhythmia 21 CFR 870.1025, MHX- Monitor, physiological, patient (with arrhythmia detection or alarm)
Intended Use	Wireless recording and display of physiological data	Wireless monitoring, recording, and analysis of physiological data	Wireless monitoring, recording, and analysis of physiological data
Intended Users	Healthcare Professionals	Healthcare Professionals	Healthcare Professionals
Intended Population	General care patients 18 years of age or older	General care patients 18 years of age or older	General care patients 18 years of age or older
Intended Use Environment	For home use and healthcare setting	For healthcare setting	For home use and healthcare setting
Hardware			
Device Placement on Human Body	Left upper chest area	Left upper chest area	Left upper chest area
Reuse	ECG Recorder: Re-usable Adhesive Patch: Single use	Sensor Module: Single use Adhesive Patch: Single use	Sensor Module: Single use Adhesive Patch: Single use

Feature/ Function	**Subject device:** VV330 Continuous ECG Platform	**Primary Predicate Device:** VitalConnect Platform (K132447)	**Secondary Predicate Device:** VitalConnect Platform (K141167)
Duration of Continuous Use	3 days of continuous recording once fully charged	4 days of continuous monitoring. Dispose after single usage	4 days of continuous monitoring. Dispose after single usage
Battery	Rechargeable battery	Single use, non-rechargeable battery	Single use, non-rechargeable battery
Accelerometer	Tri-axial accelerometer	Tri-axial accelerometer	Tri-axial accelerometer
Size and Weight	Device Size: 90mm x 28mm x7.9mm Adhesive Patch Size: 110mm x 48mm x 0.9mm (without the release liner) Device Weight: 7.5g	Device Size: ~21mm x 12mm x 4mm Adhesive Patch Size: ~111mm x 47mm x 6mm (without the release liner) Device Weight: 11g	Device Size: ~21mm x 12mm x 4mm Adhesive Patch Size: ~111mm x 47mm x 6mm (without the release liner) Device Weight: 11g
Relay Server	No	Yes	Yes
Signal Transmission	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)
Operating Temperature	10-45 degree C	10-43 degree C	10-43 degree C
Electrical Safety	Conformed to IEC 60601-1	Conformed to IEC 60601-1	Conformed to IEC 60601-1
Electromagnetic Compatibility	Conformed to IEC 60601-1-2	Conformed to IEC 60601-1-2	Conformed to IEC 60601-1-2
Software			
Heart Rate Detection Range	40-300 Bpm (beats per minute)	30-200 Bpm (beats per minute)	30-200 Bpm (beats per minute)
Heart Rate Accuracy	95% accuracy against true heart rate value under ambulatory conditions	< +/- 5 or 10% Beats per minute, whichever is greater	< +/- 5 or 10% Beats per minute, whichever is greater
R-R Interval Output	Yes	Yes	Yes
Electrocardiogram (ECG) Display	Yes	Yes	Yes
Programmable Notification and Setting	No	Yes	Yes
Configurable Software Library	Yes	Yes	Yes
Performance	Conformed to IEC 60601-2-47	Conformed to IEC 60601-2-47	Conformed to IEC 60601-2-47
Patient Contact Material			
Biocompatibility	Conformed to ISO 10993-1, ISO 10993-5 and ISO 10993-10	Conformed to ISO 10993-1, ISO 10993-5 and ISO 10993-10	Conformed to ISO 10993-1, ISO 10993-5 and ISO 10993-10

Feature/ Function	Subject device: VV330 Continuous ECG Platform	Primary Predicate Device: VitalConnect Platform (K132447)	Secondary Predicate Device: VitalConnect Platform (K141167)
Adhesive Usage	Yes	Yes	Yes

8. Performance Data

VivaLNK, Inc. ("VivaLNK") completed the appropriate design verification activities to evaluate the safety and performance of the Subject Device in accordance with the device specifications and applicable performance standards through software, hardware, mechanical, biocompatibility, packaging tests, and electromagnetic compatibility testing. These tests were performed in accordance with the following FDA recognized standards:

Standard	Title of Standard
ISO14971:2007/(R)2010 medical devices	Application of Risk Management to Medical Devices
ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices - Part 5	Tests for in vitro cytotoxicity
ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10	Tests for irritation and skin sensitization
AAMI/ANSI EC-12:2000/(R)2012	Disposable ECG electrodes
ANSI AAMI ES60601-1:2005 (Third Edition) +CORR. 1:2006 + CORR. 2:2007+A1:2012 (or IEC 60601-1:2012 reprint) Medical electrical equipment - Part 1	General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2	General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-11:2015 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
ANSI AAMI IEC 60601-2-47:2012 (Second Edition) Medical electrical equipment -- Part 2-47	Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
ANSI IEEE C63.27-2017	American National Standard for Evaluation of Wireless Coexistence

IEC 62304: 2015	Medical Device- Application of Usability Engineering to Medical Devices

9. Conclusion

The Subject VV330 Continuous ECG Platform device is substantially equivalent to the Primary Predicate VitalConnect Platform (K132447) device and is intended for the same clinical application as the predicate devices. There are minor technological/design differences that do not raise new issues of safety or effectiveness. The primary and secondary predicates share the same intended use, indications for use, intended users, intended population, and device's product code and regulation number. The secondary predicate supports home use. Based on the test results, compliance with FDA recognized industry standards, and the analysis provided in this notice, the Subject device is shown to be substantially equivalent to the Predicate devices.