February 2, 2024

Wellvii Inc
Mark Khachaturian
CEO
4521 PGA Blvd, PMB 341
Palm Beach Gardens, Florida 33418

Re: K231625
Trade/Device Name: VitalDetect
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, FLL
Dated: June 2, 2023
Received: June 2, 2023

Dear Mark Khachaturian:

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,

Robert T. Kazmierski -S

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K231625

Device Name
Wellvii VitalDetect

Indications for Use *(Describe)*
The Wellvii VitalDetect™ is a device designed for spot measurements with recorded results of non-invasive blood pressure (NIBP), pulse rate (PR), and temperature (TMP).

This device uses an infra-red sensor for non-contact temperature measurement at the forehead. All other measurements use finger-based technology.

The VitalDetectTM is applicable for prescription home use by individuals 18 years of age or older for monitoring.

The device is not intended for continuous monitoring.

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.

Section 05.01 510(k) Summary

Submitter:

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Contact Person:

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Date Prepared:

November 30th, 2023

Device Trade Name:

VitalDetect™

Common Name:

Vital Signs Monitor

Classification Name:

Noninvasive blood pressure measurement system

Classification Panel:

Cardiovascular

CFR Section:

21 CFR 870.1130 Non-invasive Blood Pressure (Cardiovascular Panel)
21 CFR 880.2910 Thermometer

Classification:

Class II

Product Codes:

DXN, Blood Pressure
FLL, Thermometer, electronic, clinical

Predicate Devices:

Primary: All-in-One Monitor (K170047)
Reference A: ARC InstaTemp MD for Temperature (K152905)

Device Description:

VitalDetect is a Bluetooth® connected, hand-held, portable vital sign monitor for prescription home use. The monitoring device can read physiological parameters, including: Pulse Rate (PR), Non-Invasive Blood Pressure (NIBP), and Body Temperature (TEMP).

The device uses a lithium-polymer battery which is rechargeable by the User. The battery is replaceable only by service personnel.

The VitalDetect monitoring system consists of a measurement device with integrated finger-clip and inflatable finger-cuff, 5 finger shims, USB charging cord, and a downloadable application (APP) for use on a mobile device.

In the home environment, the user will have responsibility for charging the device, unplugging it prior to use (to disable measurement lock), installing the app, pairing with the device, starting the app and checking the connection. The left index finger could then be placed in the correct position for the measurement process to begin.

Predicate Devices:

The Primary predicate devices is the: All-in-One Monitor (K170047). Wellvii has also identified the following reference predicate device for the temperature feature: ARC InstaTemp MD for Temperature (K152905)

Indications for Use

The Wellvii VitalDetect™ is a device designed for spot measurements with recorded results of non-invasive blood pressure (NIBP), pulse rate (PR), and temperature (TMP).

This device uses an infra-red sensor for non-contact temperature measurement at the forehead. All other measurements use finger-based technology.

The VitalDetect™ is applicable for prescription home use by individuals 18 years of age or older for monitoring.

The device is not intended for continuous monitoring.

Substantial Equivalence Comparison

Brand Name	**VitalDetect** (aka SmartVS/Vital Moto Mod)	**All-in-One Health** Monitor, PC-303	**ARC InstaTemp MD** Infrared Thermometer
General Characteristics			
Indications for Use (Clinical use)	The Wellvii VitalDetect™ is a device designed for spot measurements with recorded results of non-invasive blood pressure (NIBP), pulse rate (PR), and temperature (TMP). This device uses an infra-red sensor for non-contact temperature measurement at the forehead. All other measurements use finger-based technology. The VitalDetectTM is applicable for prescription home use by individuals 18 years of age or older for monitoring. The device is not intended for continuous monitoring.	[i]s a device designed for spot-checking measuring of the patient's physiological parameters, such as NIBP, SpO_2, PR, and body TEMP. Additionally, the device is available to communicate with the compatible Blood Glucose Monitoring System and ECG Monitor to make the measurement. This device is applicable for adult and pediatric (age ≥3 years old) use in clinical institutions and has no conditions or factors of contraindication.	The ARC InstaTemp is an infrared thermometer that measures temperature from the forehead in **both infants and adults** without contacting the human body.

Technology Characteristics Comparison				
Product	**Proposed Device**	**Primary Predicate**	**Reference A**	**Discussion**
Brand Name	**VitalDetect** (aka SmartVS/Vital Moto Mod)	**All-in-One Health** Monitor, PC-303	**ARC InstaTemp MD** Infrared Thermometer	
General Characteristics				
Manufacturer	Wellvii Inc.	Shenzhen Creative Industry Co., Ltd.	ARC Devices Ltd. (predecessor to Vital USA Inc)	
510k number	K231625	K170047	K152905	
Regulation Number	21 CFR 870.1130 Cardiovascular Devices Cardiovascular Diagnostic Devices Noninvasive BP measurement system (performance standards)	21 CFR 870.2300 Cardiovascular Devices Patient Monitor	21 CFR 880.2910 General Hospital ODE Anesthesiology, General Hospital Devices Thermometer, Electronic, Clinical	
Class and Product Code	Class II, DXN, DQA, FLL	Class II, MWI, DQA, DXN, FLL, NBW (glucose), DSH (ECG recorder)	Class II, FLL	
Patient Population	Adults aged 18 years and older	Children and adults >= 3 years old	Both Infants and Adults	(D) Patient Types: • The Proposed target population is ≥18 yrs of age. • The Predicate is targeted for those persons ≥3 years of age. • Reference Predicate B is targeted for both infants and adults. **SUMMARY**: The difference does not cause new questions regarding safety and effectiveness because they are all indicated for adults.
Parameters Measured	Heart Rate, Blood Pressure, and Temperature	Non-Invasive: BP, PR, SpO2, TEMP	Temperature	SAME
Use Location	Clinical Setting, Home Use	Clinical Setting	Clinical Setting	(D) The Proposed, Primary, and Reference devices can be used in a clinical setting. The Proposed is a prescription home use device. **SUMMARY**: The difference does not cause new questions regarding safety and effectiveness as the Proposed device was tested to Home Use standards.
Form Factor	Handheld Device	Table Top device with Accessories	Handheld Device	(S) Similar compact form factors. **SUMMARY**: The difference does not cause new questions regarding safety and effectiveness.

Power Source	Rechargeable lithium-polymer; low battery indicator,	Rechargeable lithium battery 3.7 DC or AC; low battery indicator; quick-button return to power saving mode	N/A	SAME
Temperature				
Principle of Operation	TEMP: (body) infrared radiation energy technology via the forehead; adjusted mode	N/A	TEMP: (body) infrared radiation energy technology via the forehead; adjusted mode	SAME
Measurement Range	TEMP output range: 32.0°C- 43.0°C (89.6°F – 109.4°F)	N/A	TEMP output range: 32.0°C- 43.0°C (89.6°F – 109.4°F)	SAME
Accuracy	TEMP accuracy: ±0.3°C (36.0°C to 39.0°C) ± 0.3°C (the rest) ±0.3°F (96.8°F to 102.2°F) ±0.3°F (the rest)	N/A	TEMP accuracy: ±0.3°C (36.0°C to 39.0°C) ± 0.3°C (the rest) ±0.3°F (96.8°F to 102.2°F) ±0.3°F (the rest)	SAME
Blood Pressure				
Principle of Operation	**Blood Pressure**: The finger cuff occludes blood flow and uses the oscillometric principle to estimate systolic and diastolic. Measurement can be canceled by press-and-hold of the power button.	**Blood Pressure**: The arm cuff occludes blood flow and uses the oscillometric principle to estimate systolic and diastolic. BP can be cancelled /activated by a shortcut button.	N/A	(S) The proposed devices use the oscillometric method. (D) The Proposed device measures from the finger and the Primacy predicate measures from the arm. **SUMMARY**: The differences do not raise new questions regarding safety and effectiveness because they both meet the same blood pressure accuracy standard ISO 80601-2:2018.
Measurement Range	60-230 mmHg Systolic 40-130 mmHg Diastolic	60-240 mmHg 30-180 mmHg	N/A	(D) The Primary predicate has larger systolic and diastolic range. **SUMMARY**: The differences do not raise new questions regarding safety and effectiveness because the Proposed device will not display a result if the blood pressure is out of its range.
Accuracy	**BP accuracy MDV**: ±5.0 mmHg (± 0.67 kPa) with SD: ≤ 8.0 mmHg	**BP accuracy MDV**: ±5.0 mmHg (± 0.67 kPa) with SD: ≤ 8.0 mmHg	N/A	SAME
Over Pressure Limit	Active if cuff pressure exceeds 300 mmHg (adult) at any time.	Active if cuff pressure exceeds 300 mmHg (adult and pediatric modes) at any time.	N/A	SAME
Pulse Rate				
Principle of Operation	Pulse Rate (PR), peak detection of 940 nm signal	PR: photoelectric method;	N/A	SAME

Measurement Range	40-140 bpm	PR range: 30 to 240 bpm	N/A	(D) The Primary predicate has larger measurement range. **SUMMARY**: The differences do not raise new questions regarding safety and effectiveness because the Proposed device will not display a result if the result is out of its range.
Accuracy	< ± 3.0 bpm	< ± 3 bpm	N/A	SAME

Safety and Performance Testing:

Safety and Performance testing was performed to ensure that the device operates within specified parameters independently with all other functions of the device operating and with respect to the predicate. Each function operated within the design parameters and within the performance criteria established by the pertinent regulatory standards and FDA guidance's. The result of these tests establishes substantial equivalency of the proposed device, the VitalDetect, with the predicate (and reference devices).

The following safety and performance tests were conducted to support the substantial equivalence determination and confirmed compliance as follows:

- Basic and Electrical Safety Testing has confirmed compliance to IEC 60601-1:2012 (Edition 3.1) (Attachment 17.02)
- Electromagnetic Compatibility (EMC) Testing has confirmed compliance to:
  - IEC 60601-1-2:2014-02 (Edition 4.0)
  - ETSI EN 301 489-1 V2.1.1 (2017-02)
  - ETSI EN 301 489-17 V3.1.1 (2016-11)
  - FCC Part 15.247

  See Attachment 17.04.
- Rechargeable Lithium-Polymer Battery Testing testing for the VitalDetect battery has confirmed compliance to:
  - IEC 62133-2:2017 (Attachment 17.06)
  - EN 61000-6-1:2007 (Attachment 17.07)
  - EN 61000-6-3:2007(Attachment 17.07)
  - UN 38.3/Amendment 1 (Attachment 17.08)
- General Safety testing with regard to Usability has confirmed compliance with Collateral Standard IEC 60601-1-6:2013 (Edition 3.1) (Attachment 18.02).
- Wireless Co-existence testing: VitalDetect ANSI C63.27 Tier 2
- Home Healthcare Testing has confirmed compliance with IEC 60601-1-11:2015 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. (Attachment 17.03)
- Testing for ingress protection has confirmed a rating of IP22 according to IEC 60529:2013 (Edition 2.2). (Attachment 17.02)
- Multi-function Patient Monitoring testing has confirmed compliance with IEC 80601-2-30:2009 (Attachment 18.03).
- Thermometer Testing has confirmed compliance with ISO 80601-2-56:2017 Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. (Attachment 18.05)
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- Blood Pressure Testing was performed according to IEC 80601-2-30:2018. Medical electrical equipment – Part 2-30 Particular requirements for basic safety and essential performance of automated noninvasive sphygmomanometers. The VitalDetect showed

compliance with basic safety and accuracy requirements of the standard. (Attachment 18.03)

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- Packaging testing of the VitalDetect unit packaging compliance to the ISTA 2A:2011 standard. (D0000458-RPT-ISTA-2A Perf Assess - Executed - SN47).
- Clinical Testing (Section 20). Clinical trials were completed to validate the clinical accuracy and functionality of the proposed device. The study was conducted in accordance with 21 CFR 812 for Non-significant Risk Investigational Studies, following ISO 14155:2011 *Clinical Investigation of medical devices for human subjects – Good clinical practice*, as appropriate. The table below summarizes the study results.

Vital Sign	Accuracy	Range
NIBP - Systolic	Criterion 1: +1.66 mmHg Bias Criterion 1: ± 7.67 mmHg STD Criterion 2: ± 6.49 mmHg STD	60-230 mmHg
NIBP – Diastolic	Criterion 1: +1.04 mmHg Bias Criterion 1: ± 6.49 mmHg STD Criterion 2: ± 5.67 mmHg STD	40-130 mmHg
Pulse Rate	± 2.7 Arms	40-140 bpm
Temperature	± 0.3 ºC	32-43 ºC

- Risk Management activities have confirmed compliance to ISO 14971:2007 and EN 14971:2012. The risk management file was updated for the addition of the finger shims.
- Biocompatibility Testing. The VitalDetect™ is a surface-contacting device with less than 24 hours contact duration. The patient-contacting materials were tested in accordance with ISO 10993-1 for cytotoxicity, irritation and sensitization.

  ISO 10993-5. Biological evaluation of medical devices – Part 5: Tests for in-vitro cytotoxicity. The purpose of this study was to determine the potential of a test article extract to cause cytotoxicity. Under the conditions of this study, the test article extract showed no evidence of causing cell lysis or toxicity and met the requirements of the test since the grade was less than a grade 2 (mild reactivity). (Attachment 15.01)

  ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization. The purpose of this test is to evaluate the potential of a test article to cause skin irritation and sensitization in the guinea pig. Under the conditions of these studies, the test article extracts showed no significant evidence of causing skin sensitization (in the guinea pig) and the irritation response was negligible and met the requirements of the tests. (Attachment 15.02, Attachment 15.03). Additionally, a chemical analysis was performed on the extractions to show that they were not the result of poor manufacturing techniques (Attachment 15.05) and a risk assessment was performed of finger shim materials (Attachment 15.06).

Conclusion:

In accordance with the Federal, Food, Drug and Cosmetic Act, 21 CFR 807 and based on the information and objective evidence provided in this premarket notification, Wellvii Inc concludes that the VitalDetect™ device is substantially equivalent to the predicate device as described herein.