May 20, 2021

VoCare, Inc.
Deon Vigilance
Chief Medical Officer
4950 Turkey Foot Road
Zionsville, Indiana 46077

Re: K210086
Trade/Device Name: Vitals360® Multi-Vitals Mobile Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, DSH, DXN, FLL
Dated: April 19, 2021
Received: April 19, 2021

Dear Deon Vigilance:

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

LT 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)*
K210086

Device Name
Vitals360® Multi-Vitals Mobile Monitor

Indications for Use *(Describe)*
Vitals360® device is intended to be used for measuring, displaying, reviewing and storing of non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), forehead temperature (TEMP), ECG, weight and height in adults no less than 18 years of age.

This VITALS360® device is intended for use by trained adults only who can use smartphones proficiently.

This VITALS360® device is intended for use in a clinical or home environment.

This VITALS360® device is a reusable device following thorough cleaning between uses.

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.

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510(k) SUMMARY – K210086

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Contact Person: Steve Peabody

VoCare, Inc.

4950 Turkey Foot Road

Zionsville, IN 46077 USA

Tel: +1 (317) 658-0005

Fax: N/A

Submission Contact: Deon Vigilance

Date Prepared: April 15, 2021

II. DEVICE

Name of Device:	Vitals360® Multi-Vitals Mobile Monitor – Model: VC-001
Classification Name:	Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)
Regulation:	21 CFR §870.2300
Regulatory Class:	Class II
Product Classification Code:	MWI, DQA, DSH, DXN, and FLL

III. PREDICATE DEVICE

Primary Predicate Manufacturer:	Shenzhen Creative Industry Co., Ltd.
Primary Predicate Trade Name:	All-in-One Health Monitor, PC-303
Primary Predicate 510(k):	K170047
Secondary Predicate Manufacturer:	Ningbo Ranor Medical Science & Technology Co., Ltd.
Secondary Predicate Trade Name:	Infrared Thermometer, RN-50A, RN-50B
Secondary Predicate 510(k):	K200578

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Vitals360® is a device designed for spot-checking measuring of the patient's physiological parameters. It

can monitor the patient's blood oxygen saturation (SpO2) and pulse rate (PR) non-invasively by the photoelectric method. It can also measure non-invasive blood pressure (NIBP, the pressures of systolic and diastolic) by the oscillating method and body temperature (TEMP) by the infrared radiation energy technology. Additionally, it can record single lead ECG signal.

The Vitals360® capabilities include storing, displaying measuring data.

V. INTENDED USE & INDICATION FOR USE

Vitals360® device is intended to be used for measuring, displaying, reviewing and storing of non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), forehead temperature (TEMP), ECG, weight and height in adults no less than 18 years of age.

This VITALS360® device is intended for use by trained adults only who can use smartphones proficiently.

This VITALS360® device is intended for use in a clinical or home environment.

This VITALS360® device is a reusable device following thorough cleaning between uses.

VI. COMPARISON TO THE PREDICATE DEVICE

Features	Subject Device - Vitals360	Primary Predicate Device - PC-303 (K170047)	Secondary Predicate Device – Infrared Thermometer RN-50A, RN-50B (K200578)	Justification for Differences
Applicant	VoCare Inc.	Shenzhen Creative Industry Co., Ltd.	Ningbo Ranor Medical Science & Technology Co., Ltd.	N/A
Classification Regulation	21 CRF 870.2300	21 CRF 870.2300	21 CFR 880.2910	The secondary predicate is limited to the regulation for clinical thermometers.
Classification and Code	Class II, MWI, DQA, DSH, DXN, and FLL	Class II, MWI, DQA, DXN, FLL, NBW, DSH	Class II, FLL	The subject device does not include a glucometer function, and therefore the NBW code is not applicable to the subject device. The secondary predicate is limited to the clinical thermometer product code.
Common name	Patient Monitor	Patient Monitor	Thermometer, electronic, clinical	The secondary predicate is limited to the clinical thermometer function.
Intended use	Vitals360® device is intended to be used for measuring, displaying, reviewing and storing of non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), forehead temperature (TEMP), ECG, weight and height in adults no less than 18 years of age. This VITALS360® device is intended for use by trained adults only who can use smartphones	The All-in-One Health Monitor, PC- 303 is a device designed for spot- checking measuring of the patient's physiological parameters, such as Non-Invasive Blood Pressure (NIBP), Oxygen saturation (SpO2), Pulse Rate (PR) and Body Temperature (TEMP); Additionally, the device is available to communicate with the compatible Blood Glucose Monitoring System and ECG	The Infrared thermometer is a non-contact infrared thermometer intended for the intermittent measurement of human body temperature from forehead for people of all ages. The device is reusable for home use and clinical use.	The subject device is limited to patients 18 years of age and older and does not include indications for glucose measurement. These omissions do not introduce any additional risks, and otherwise the indications are equivalent to the primary predicate. The secondary predicate is limited to body temperature measurement and also applies to a wider patient range.

	proficiently. This VITALS360® device is intended for use in a clinical or home environment. This VITALS360® device is a reusable device following thorough cleaning between uses.	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.		
Physical dimension(mm) /weight(kg)	145(L) × 80(W) × 25(H) / 0.25kg	165(L) × 96(W) × 68(H) / 0.44kg	N/A	The subject device is smaller that the primary predicate which does not create any negative issues regarding portability or usability of the device, and the smaller size of the clinical thermometer is due to its limited functionality.
Display	3.66 inch	4.3 inch	LCD Display	The display size of the subject device and the predicate are equivalent, and no readability issues were identified during usability testing. The LCD display for the clinical thermometer is appropriate only for the display of a single temperature.
Type, Degree of protection against electric shock	Class II with internal electric power supply. SpO2/NIBP/TEMP: Type BF applied part.	Class II with internal electric power supply. SpO2/NIBP/TEMP: Type BF applied part.	Class II with internal electric power supply. TEMP: Type BF applied part.	The subject device and the primary predicate are identical. The applicable applied part of the subject device is also equivalent to the clinical thermometer.
Power supply	Battery or AC	Battery or AC	Battery	The subject device and the primary predicate are identical. The lack of AC charging for the clinical thermometer is appropriate for the lower power requirements.

Power requirement	(100-240) VAC, 50/60Hz, 0.5A, Rechargeable lithium battery, 3.7VDC	(100-240) VAC, 50/60Hz, 15VA, Rechargeable lithium battery, 3.7VDC	AAA*3, DC 3V	The subject device and the primary predicate are equivalent. The lack of AC charging for the clinical thermometer is appropriate for the lower power requirements.
Alarm	No alarm	No alarm	Low Battery Indication	The subject device and primary predicate do not include alarms for low battery indication, because the display is able to show a battery icon that indicates the remaining battery % and the device will not take measurements if the battery level is too low.

Features	Subject Device - Vitals360	Primary Predicate Device - PC-303 (K170047)	Secondary Predicate Device – Infrared Thermometer RN-50A, RN-50B (K200578)	Justification for Differences
SpO2 / Pulse Rate				
Patient	18 years and older	Adult, pediatric	Adult, pediatric	The subject device is limited to patients 18 years of age and older, while both predicates are indicated for adult and pediatric patients. This omission does not introduce any additional risks.
SpO2 measurement accuracy	Displayed range: 70%~100% ±2% (during 90~100%), ±4% (during 70~89%)	Displayed range: 70%~100% ±3% (during 70%-100%) Undefined (during 0-70%)	N/A	Subject device and primary predicate are equivalent, and secondary predicate does not include SpO2 feature.
Pulse rate measurement range	30 to 150 bpm	30 bpm-240 bpm	N/A	Subject device and primary predicate are equivalent, and secondary predicate does not include SpO2 feature.
Pulse rate accuracy	±2bpm or ±2%, whichever is greater	±2bpm or ±2% (whichever is greater)	N/A	Subject device and primary predicate are identical, and

				secondary predicate does not include SpO2 feature.
Alarm	No alarm	No alarm	N/A	Subject device and primary predicate are identical, and secondary predicate does not include SpO2 feature.

Features	Subject Device - Vitals360	Primary Predicate Device - PC-303 (K170047)	Secondary Predicate Device – Infrared Thermometer RN-50A, RN-50B (K200578)	Justification for Differences
NIBP				
Method	Oscillometric method	Oscillometric method	N/A	Subject device and primary predicate are identical, and secondary predicate does not include NIBP feature.
Patient type	18 years and older	Adult and Pediatric patients	N/A	The subject device is limited to patients 18 years of age and older and does not include indications for glucose measurement. These omissions do not introduce any additional risks, and otherwise the indications are equivalent to the primary predicate. The secondary predicate does not include NIBP feature.
Unit of measure	mmHg & kPa	mmHg & kPa	N/A	Subject device and primary predicate are identical, and secondary predicate does not include NIBP feature.
Pressure measurement range - Systolic	60 mmHg ~230mmHg	60 mmHg - 255mmHg	N/A	Subject device and primary predicate are equivalent, and secondary predicate does not include NIBP feature.
Pressure measurement range - Diastolic	40 mmHg ~130mmHg	30 mmHg - 195mmHg	N/A	Subject device and primary predicate are equivalent, and secondary predicate does not

				include NIBP feature.
BP accuracy	Mean deviation values: ±5 mmHg. Standard deviation <= 8 mmHg.	Mean deviation values: ±5 mmHg. Standard deviation <= 8 mmHg.	N/A	Subject device and primary predicate are identical, and secondary predicate does not include NIBP feature.
Cuff pressure range	0 to 300mmHg	0 to 300mmHg	N/A	Subject device and primary predicate are identical, and secondary predicate does not include NIBP feature.
Over pressure protector	Cuff pressure exceeds 300mmHg at any time.	Cuff pressure exceeds 300mmHg (Adult and pediatric mode) at any time.	N/A	Subject device is limited to subjects 18 years an older, while the primary predicate is indicated for adult and pediatric patients. The secondary predicate does not include NIBP feature.
Alarm	No alarm	No alarm	N/A	Subject device and primary predicate are identical, and secondary predicate does not include NIBP feature.

Features	**Subject Device - Vitals360**	**Primary Predicate Device - PC-303 (K170047)**	**Secondary Predicate Device – Infrared Thermometer RN-50A, RN-50B (K200578)**	**Justification for Differences**
TEMP				
Fundamental scientific technology	Infrared technology	Infrared technology	Infrared technology	All three devices are identical with regard to technology.
Patient type	18 years and older	Adult, Pediatric	Adult, Pediatric	The subject device is limited to patients 18 years of age and older, while both predicates are indicated for adult and pediatric patients. This omission does not

				introduce any additional risks.
Unit of measure	°C or °F	°C or °F	°C or °F	All three devices are identical with regard to unit of measure.
Measurement site	Forehead	Ear	Forehead	The secondary predicate was selected, because the primary predicate uses a different measurement site. The secondary predicate and the subject device are identical with regard to measurement site.
Temperature measurement range	34.0°C ~43.0°C(93.2°F~109.4°F)	32.0°C to 43.0°C (90°F to 109.4°F)	32.0°C ~42.9°C (89.6°F~109.2°F)	The temperature ranges of all three devices are slightly different, but they are equivalent and meet the requirements of the applicable standards for clinical thermometers.
Temperature measurement accuracy	±0.3°C (±0.5°F)	±0.2°C (36.0°C to 39.0°C), ±0.3°C other range	±0.2°C (36.0°C to 39.0°C) ±0.3°C other range	The temperature accuracy of the subject device is equivalent to both predicates, and all three devices meet the requirements of the clinical thermometer standards.

Features	**Subject Device - Vitals360**	**Primary Predicate Device - PC-303 (K170047)**	**Secondary Predicate Device – Infrared Thermometer RN-50A, RN-50B (K200578)**	**Justification for Differences**
ECG				
Patient type	18 years and older	Adult, pediatric patients	N/A	The subject device is limited to patients 18 years of age and older, while both predicates are indicated for adult and pediatric patients. This omission does not introduce any additional risks.
Number of electrodes employed	2 embedded metal electrodes	3 embedded metal electrodes or using 3 adhesive ECG electrodes by	N/A	Subject device and primary predicate are equivalent, and secondary predicate does not

		connection to the lead wire		include ECG feature.
Heart rate measuring range	30bpm-240bpm	30bpm-240bpm	N/A	Subject device and primary predicate are identical, and secondary predicate does not include ECG feature.
Resolution	1bpm	1bpm	N/A	Subject device and primary predicate are identical, and secondary predicate does not include ECG feature.
Heart rate measuring precision	±2bpm or ±2%, whichever is greater	±2bpm or ±2%, whichever is greater	N/A	Subject device and primary predicate are identical, and secondary predicate does not include ECG feature.
Sweep speed	25mm/s, 50mm/s	20mm/s±10%	N/A	Subject device and primary predicate are equivalent, and secondary predicate does not include ECG feature.
Signal bandwidth	0.67Hz-40Hz	0.5Hz-40Hz	N/A	Subject device and primary predicate are equivalent, and secondary predicate does not include ECG feature.
Internal noise level	≤50uV p-v	≤30uVp-p	N/A	Subject device and primary predicate are equivalent, and secondary predicate does not include ECG feature.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for VC-001 was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The subject devices are considered surface contacting for a duration of not exceed 24 hours.

Non-clinical data

The Pulse Oximeter has been tested according to the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, 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
- 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.
- IEC 60601-2-47: 2012 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of ambulatory electrocardiographic systems.
- ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.
- ISO 80601-2-30: 2018 Medical Electrical Equipment - Part 2-30: Particular Requirements for Basic Safety and Essential Performance of automated non-invasive sphygmomanometers.
- ISO 80601-2-56: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of clinical thermometers for body temperature measurement.
- IEC 62133: 2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

  The test was selected to show substantial equivalence between the subject device and the predicate.

Clinical data

Clinical studies were conducted to verify the accuracy of proposed device. The clinical studies were conducted per following standards:

- ISO 80601-2-61: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment.

- Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff
- ISO 81060-2: 2018 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type
- ISO 80601-2-56: 2017 Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of clinical thermometers for body temperature measurement.

Clinical testing has been performed under an approved protocol with subject informed consent. Clinical test results support device accuracy claims for the specified measurement range.

VIII. CONCLUSION

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate devices.