June 6, 2018

TaiDoc Technology Corporation
Anne Kuo
Regulatory Affairs Specialist
6F, No. 127, Wugong 2nd Rd., Wugu District
New Taipei City, Taiwan 24888

Re: K172221
Trade/Device Name: VTRUST Vital Signs Monitor, Model: TD-2300; FORA Vital Signs Monitor, Model: VSM100
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, DXN, FLL, NBW, LFR, DPS
Dated: May 1, 2018
Received: May 4, 2018

Dear Anne Kuo:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172221

Device Name
VTRUST Vital Signs Monitor, Model: TD-2300
FORA Vital Signs Monitor, Model: VSM100

Indications for Use *(Describe)*
The Vital Signs Monitor is intended for the monitoring of parameters such as ECG, non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, body temperature, blood glucose and oxygen saturation of arterial hemoglobin (SpO2) of adult patient. The monitor is intended to be used by clinicians and medically qualified personnel and trained users.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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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."

510(k) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K172221

1. Submitter Information

Company Name:	TaiDoc Technology Corporation
Address:	6F, No. 127, Wugong 2nd Rd., Wugu Dist., New Taipei City, Taiwan 24888
Contact Person:	Anne Kuo
Title:	Regulatory Affairs Specialist
Phone:	+886-2-6625-8188 #1195
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E-mail:	Anne.Kuo@taidoc.com.tw

2. Proposed Device Information:

Trade/Device Name:	VTRUST Vital Signs Monitor, Model: TD-2300 FORA Vital Signs Monitor, Model: VSM100	
Regulation Name:	Monitor, physiological, patient (without arrhythmia detection or alarms)	
Regulatory Class:	Class II	
Regulation Number:	21 CFR §870.2300	
Review Panel:	Cardiovascular	
Product Code:	MWI	
Subsequent Product Codes:	DPS	Electrocardiograph
	DQA	Oximeter
	DXN	System, measurement, blood-pressure, non-invasive
	FLL	Thermometer, Electronic, Clinical
	NBW	Blood Glucose Test System, Over-the-Counter
	LFR	Glucose Dehydrogenase

Subsequent Regulation Number:	21 CFR §870.2340	Electrocardiograph
	21 CFR §870.2700	Oximeter
	21 CFR §870.1130	Noninvasive blood pressure measurement system
	21 CFR §880.2910	Clinical electronic thermometer
	21 CFR §862.1345	Glucose test system

3. Intended Use:

The Vital Signs Monitor is intended for the monitoring of parameters such as ECG, non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, body temperature, blood glucose and oxygen saturation of arterial hemoglobin (SpO2) of adult patient. The monitor is intended to be used by clinicians and medically qualified personnel and trained users.

4. Device Description:

The Vital Signs Monitor is intended for the monitoring of parameters such as ECG, non-invasive blood pressure (systolic, diastolic, and mean arterial pressure), pulse rate, body temperature, blood glucose and oxygen saturation of arterial hemoglobin (SpO2) of adult patient. The monitor is intended to be used by clinicians and medically qualified personnel and trained users.

The body temperature and blood glucose measurements are cleared by FDA under k101259 and k120042 respectively.

VTRUST Vital Signs Monitor and **FORA Vital Signs Monitor** are exactly identical in design technical and physical appearance. The only difference is the brand name and model name.

5. Substantial Equivalence Information:

Primary predicate device	V-TRUST Model TD-8002 Multi-Parameter Spot Check Monitor k101259
Subsequent Predicate Device (ECG)	V-TRUST TD-2202 Portable ECG Recorder k101569
Subsequent Predicate Device (Blood Glucose)	TD-4268 Blood Glucose Monitoring System TD-4268 Multi Blood Glucose Monitoring System k120042
Similarities	ECG technology

	NIBP technology SpO2 technology Blood glucose technology Temperature technology Data transmission Power source

6. Test Principle:

The V**ital Signs Monitor** applies the same test principle as those of the predicate devices. No changes were made in the peripheral blood glucose meter and thermometer.

7. Safety and Effectiveness Characteristics:

The evaluation of safety, electromagnetic compatibility, biocompatibility, and software validation of the **Vital Signs Monitor** were conducted based on the following standards:

Standard	**Title**
IEC 60601-1	Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-27	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 60601-2-49	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
IEC 62304	Medical device software - Software life-cycle processes
IEC 80601-2-30	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

ISO 80601-2-61	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 10993 series	Biological evaluation of medical devices
ISO 14971	Medical device - Application of Risk Management to Medical Devices

8. Performance Bench Testing:

The laboratory and clinical evaluations for the performance of **Vital Signs Monitor** demonstrate that the modifications do not impact on the effectiveness. The performance of this system meets its intended use and is equivalent to the predicated devices.

Description	**Test Objective**
ECG performance testing	To ensure the ECG performance meets the specification cleared under k101569.
SpO_2 performance testing	To ensure the SpO_2 performance meets the specification cleared under k101259.
NIBP performance testing	To ensure the NIBP performance meets the specification cleared under k101259.
Blood Glucose performance testing	To ensure the blood glucose performance meets the specification cleared under k120042.
Thermometer performance testing	To ensure the thermometer performance meets the specification cleared under k101259.
Clinical Evaluation	To ensure the device performance complies with the designed specification.

9. Conclusion:

Based on the information provided in this submission, the Vital Signs Monitor is believed to be substantially equivalent with the predicate devices.