DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 2, 2016

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

Re: K151024
Trade/Device Name: Finger Type Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 7, 2015
Received: February 29, 2016

Dear Sharon Peng:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental 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)*
K151024

Device Name
Finger Type Pulse Oximeter

Indications for Use *(Describe)*
The Finger Type Pulse Oximeter is indicated for use in measuring oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. It is intended for patients during no-motion condition. The patients are limited to adults with weight above 40 kg.

This device is indicated for non-invasive spot checking.

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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: k151024

1. Submitter Information

Company Name:	TaiDoc Technology Corporation
Contact Person:	Sharon Peng
Title:	Regulatory Affairs Specialist
Address:	6F, No. 127, Wugong 2nd Rd., Wugu District, New Taipei City, 24888, Taiwan
Phone:	+886-2-6625-8188 # 1176
Fax:	+886-2-6625-0288
E-mail:	sharon_peng@taidoc.com.tw
Prepared Date:	March 2, 2016

2. Device name:

Proprietary Name:	Finger Type Pulse Oximeter
Common Name:	Pulse Oximeter
Product Code:	DQA
Classification Panel:	Anesthesiology
Classification:	Class II
Regulation Citation:	21 CFR §870.2700, Oximeter

3. Primary Predicate Device

Proprietary Name:	VTRUST Finger Type Pulse Oximeter
510(k) Number:	k110893

4. Intended Use

The **Finger Type Pulse Oximeter** is indicated for use in measuring oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. It is intended for patients during no-motion condition. The patients are limited to adults with weight above 40 kg.

This device is indicated for non-invasive spot checking.

5. Device Description:

The main function of **Finger Type Pulse Oximeter** is same as the predicate's to monitor the oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. Except for the general feature, **Finger Type Pulse Oximeter** also has the wireless data transmission function which transmits the readings of SpO_2 and pulse rate from the **Finger Type Pulse Oximeter** to the personnel device via Bluetooth pairing. The personnel device may include the smart phone, tablet PC and so on.

6. Test Principle:

The **Finger Type Pulse Oximeter** determines functional oxygen saturation of arterial hemoglobin (SpO_2) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.

7. Substantial Equivalence Information:

Predicate device name: VTRUST Finger Type Pulse Oximeter

Predicate K number: k110893

Comparison with predicated device:

The modified **Finger Type Pulse Oximeter** have the following similarities to the predicate device:

- same operating principle
- same fundamental scientific technology
- same intended use

The modified **Finger Type Pulse Oximeter** encompass the following modification to the predicate device:

- accuracy
- operating and storage specification
- physical appearance
- data transmission function
- software
- water resistance level

A comparison table that described similarities and modifications is briefly provided below:

Item	**Predicate device**	**Proposed device**
Product Name	VTRUST Finger Type Pulse Oximeter (K110893)	Finger Type Pulse Oximeter
Similarity		
Detection method	Spectrophotometry	Spectrophotometry
Power source	Two AAA alkaline batteries	Two AAA alkaline batteries
Detection mode	Spot checking	Spot checking
Range of oximetry	0% to 100%	0% to 100%
Resolution of oximetry	1%	1%
Method	Dual wavelength LED	Dual wavelength LED
Measurement Range of pulse rate	30 to 250 beats per minutes (bpm)	30 to 250 beats per minutes (bpm)
Resolution of pulse rate	1 bpm	1 bpm
Accuracy of pulse rate	±1bpm or ±1%, whichever is greater	±1 bpm or ±1% whichever is greater
Type	LCD Display with white backlight	LCD Display with white backlight
Parameters	SpO_2; pulse rate; pulse bar	SpO_2; pulse rate; pulse bar
Status	Indicate a stable reading is taken; Battery status indication	Indicate a stable reading is taken; Battery status indication
Memory	None	None
Power button	Yes	Yes
SpO_2 % display	Yes	Yes
Pulse amplitude indicator	Yes	Yes
Pulse rate display	Yes	Yes
Low battery indicator	Yes	Yes
Sensor error indicator	Yes	Yes
Display	LCD	LCD

Modification		
Accuracy of oximetry	70% to 100%: ± 2% <69%: unspecified	100% ~ 80% ±2%; 79% ~ 70% ±3%; others are undefined
Operating Condition	50°F to 104°F (10°C to 40°C); below 90% R.H. (non-condensing)	50°F to 104°F (10°C to 40°C); below 95% R.H. (non-condensing)
Storage Condition	-4ºF to 122ºF (-20ºC to 50ºC); 15% to 90% R.H. (non-condensing)	-13˚F to 158˚F (-25ºC to 70ºC); below 95% R.H. (non-condensing)
Water resistant level	IP56	IP22
Uploading	NA	Instant readings uploading via Bluetooth
Rotation	None	180 degrees
Medium Priority Alarm	None	Visual alarm (Blinking RED backlight)
Dimensions:	62.0mm (L) x 37.7mm (W) x 37.4mm (H)	63mm (L) x 37mm (W) x 32mm (H)
Weight (g)	<39g (without batteries)	Without batteries: 40g

For testing according to the above modification, please see below table

Modification	**Validation Report**
accuracy	Accuracy study report
operating and storage condition	Meter reliability report
device dimension and weight	Electrical safety, EMC, and biocompatibility test reports
software	Software validation report
water resistance level	Electrical safety test report

According to these reports, it demonstrates that the **Finger Type Pulse Oximeter** does not raise new questions of safety and effectiveness.

8. Functional and Safety Testing:

The **Finger Type Pulse Oximeter** is designed and tested in accordance with following standards.

The accuracy study was performed to demonstrate the **Finger Type Pulse Oximeter** meet the criteria of ISO 80601-2-61:2011. The evaluation study is compliance with the standard.

The laboratory testing of electrical safety, electromagnetic compatibility, and shock and vibration meet the relevant requirements of the applicable recognized standard: IEC/EN 60601-1, IEC/EN 60601-1-2 and ISO 80601-2-61.

The software validation was performed to verify and validate the proposed device works functionally and is in compliance with FDA Guidance for the Content of the Premarket Submissions for Software Contained in Medical Devices.

The skin contacting material (silicone) included in the SpO_2 probe meets the requirement of the biocompatibility standard, ISO 10993-5:2009 and ISO 10993-10:2010. The tests were performed by MedGaea Life Sciences Institute compiling with U.S. FDA (21 CFR Part 58) on principles of Good Laboratory Practice for Nonclinical Laboratory Studies. The cytotoxicity test is performed to investigate that the skin contacting material is considered non-cytotoxicity and met the requirements of ISO 10993-5:2009. The skin contacting material revealed no evidence of causing cytotoxicity and did not induce the morphologic changes of cells.
The irritation and skin sensitization tests are executed to evaluate the possibility of local inflammation after a single topical application and the possible response of skin sensitization of skin contacting material. Both studies met the requirements of ISO 10993-10:2010 and the results indicated that the skin contacting material did not cause skin irritation and sensitization.

The clinical evaluation was conducted and the result of **Finger Type Pulse Oximeter** is in compliance with the criteria of ISO 9919 standard and FDA guidance - "Pulse Oximeter Premarket Notification Submissions". The functional oxygen saturation (SpO_2) measurement has been validated on a total of 14 healthy adult male and female volunteers with 7 dark, 6 intermediate, and 1 light skin pigmentations in the range of 70% to 100%.

The SpO_2 accuracy result include that the SpO_2 value range from 70% to 79% is within

3% and the SpO_2 range from 80% to 100% is within 2%. The accuracy of SpO_2 to be ±3 dig % was verified over the range of 70% to 100%. The heart rate is within the acceptance criteria of ±1 dig bpm difference. And the root-mean-square (Arms) value is 2.0 with the saturations form 70% to 100%.

9. Conclusion

The proposed devise of **Finger Type Pulse Oximeter** has the same classification information, same intended use, same test principle and similar product design and specifications with the predicate device except the data transmission and alarm function. Based on the information provided in this submission, the **Finger Type Pulse Oximeter** is substantially equivalent to the predicate VTRUST Finger Type Pulse Oximeter (k110893).