February 12, 2019

TaiDoc Technology Corporation
Sophia Wu
Regulatory Affairs Specialist
6F, No. 127, Wugong 2nd Rd., Wugu District
New Taipei City, 24888
TAIWAN

Re: K182934
Trade/Device Name: FORA P100 Blood Pressure Monitoring System
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 19, 2018
Received: October 22, 2018

Dear Sophia Wu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Stephen C. Browning -S5

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182934

Device Name
FORA P100 Blood Pressure Monitoring System

Indications for Use *(Describe)*
The FORA P100 Blood Pressure Monitoring System is intended to be used to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. Do not use this system on babies, young children or persons who cannot express their consent.

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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Section9
510(k) Summary

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

The Assigned 510(k) number is: **K182934**

1. Submitter Information:

Company Name	TaiDoc Technology Corporation
Address	6F, No. 127, Wugong 2nd Rd., Wugu District, New Taipei City, 24888, Taiwan
Establishment Registration No.	3004145393
Date Prepared	October 19th, 2018
Contact Person	Sophia Wu
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2. Proposed Device Information:

Trade/Proprietary Name	FORA P100 Blood Pressure Monitoring System
Model Number	P100
Common Name	Blood Pressure Monitoring System
Product Code	DXN
Classification Panel	74, Cardiovascular
Classification	Class II
Regulation citation	21 CFR §870.1130, Non-invasive Blood Pressure Measurement System

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3. Predicate Device:

Trade/Proprietary Name	FORA CARE BLOOD PRESSURE MONITORING SYSTEM
Common Name	Blood Pressure Monitoring System
Submitter	TaiDoc Technology Corporation
510(k) Number	K133588

4. Intended Use

The FORA P100 Blood Pressure Monitoring System is intended to be used to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. Do not use this system on babies, young children or persons who cannot express their consent.

5. Device Description:

FORA P100 Blood Pressure Monitoring System (Model: P100) can be operated by the device itself to assist in blood pressure testing, recording, tracking and monitoring in easy.

The **TD-3130** in report is an internal model and **FORA P100** is the marketing name for this system.

6. Test Principle:

Blood pressure is measured non-invasively at the arm based on oscil-lometric method.

For people of common arrhythmia, such as atrial or ventricular pre-mature beats or atrial fibrillation, we recommend to use auscultatory mode. The reading obtained by single and average mode which use oscillometic method is for reference only and should be discussed with the healthcare professionals.

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7. Substantial Equivalence Information:

Similarities	Modifications
• Operating principle • Detection method / scientific technology • Employs the same test strip • Narrower intended use	• Meter appearance • Power source • User interface • Speaking function

Predicate device name	FORA CARE BLOOD PRESSURE MONITORING SYSTEM
Predicate K number	K133588
Comparison with predicate	The modified FORA P100 Blood Pressure Monitoring System has the following similarities to the predicate device: ■ same intended use, ■ same operating principle, ■ same fundamental scientific technology, ■ incorporate the same basic circuit design, ■ incorporate the same materials, ■ manufactured by the same process. The modifications encompass: ■ Meter memory ■ Speaking function ■ Modification of the devices physical appearance ■ Labeling change due to the above modifications

The FORA P100 Blood Pressure Monitoring System and the predicate device both use the oscillometric method within the software algorithm to determine the systolic, diastolic blood pressure and pulse rate with an inflatable arm cuff. The major difference between the two devices is physical appearance of device. The minor changes are software.

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8. Performance Characteristics:

The FORA P100 Blood Pressure Monitoring System was validated by the tests according to IEC 80601-2-30:2009 and met the requirements of ANSI/AAMI/ISO 81060-2:2009.

Software validation was performed to verify and validate the system works functionally.

Testing performed included electrical safety, EMC, and shock and vibration test. The proposed device met the requirements of IEC/EN 60601-1, IEC/EN 60601-1-2 and IEC/EN 60601-1-11.

Biocompatibility testing was also performed. The materials of cuff met the requirements of ISO 10993-5 and 10993-10.

The FORA P100 Blood Pressure Monitoring System has the same performance characteristics as the predicate device. Software verification and validation, and design validation confirmed that the performance, safety and effectiveness of the FORA P100 Blood Pressure Monitoring System are substantial equivalent to the predicate device.

9. Conclusion:

Based on the information provided in this submission, the FORA P100 Blood Pressure Monitoring System is substantially equivalent to the predicate FORA CARE BLOOD PRESSURE MONITORING SYSTEM.