July 12, 2018

TaiDoc Technology Corporation
Anne Kuo
Scientific Reviewer
B1-7F, No. 127, Wugong 2nd Rd.
Wugu District
New Taipei City 24888, Taiwan

Re: K173511
Trade/Device Name: ActiveCare TD-4121 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: June 9, 2018
Received: June 13, 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 and Part 809); 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,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
k173511

Device Name
ActiveCare TD-4121 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The ActiveCare TD-4121 Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) in the quantitative measurement of glucose in fresh capillary whole blood taken from the finger. It is intended to be used by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.

The ActiveCare TD-4121 Blood Glucose Monitoring System is comprised of the ActiveCare TD-4121 glucose meter and the ActiveCare TD-4121 blood glucose test strip.

The ActiveCare TD-4121 Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The ActiveCare TD-4121 Blood Glucose Monitoring System is not intended for the diagnosis of, or screening of diabetes. It is not intended for use on neonates.

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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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: K173511

1. Submitter information

Company name	TaiDoc Technology Corporation
Address	B1-7F, No. 127, Wugong 2nd Rd., Wugu District, New Taipei City, 24888, Taiwan
Phone	+886-2-6625-8188 #1195
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Contact person	Anne Kuo
Title	Regulatory Affairs Senior Specialist
E-mail	anne.kuo@taidoc.com.tw ra.cert@taidoc.com.tw
Prepared date	June 09, 2018

2. Device name

Proprietary name	ActiveCare TD-4121 Blood Glucose Monitoring System
Common name	Blood Glucose Monitoring System
Product code	NBW, Blood Glucose Test System, Over-the-Counter
Classification panel	Clinical chemistry
Classification	Class II
Regulation citation	21 CFR §862.1345, Glucose test system

3. Predicate Device

Proprietary Name:	TD-4277 Blood Glucose Monitoring System
Common Name:	Blood Glucose Monitoring System
510(k) Number:	K100322

4. Intended use

The ActiveCare TD-4121 Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use) in the quantitative measurement of glucose in fresh capillary whole blood taken from the finger.

It is intended to be used by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.

The ActiveCare TD-4121 Blood Glucose Monitoring System is comprised of the ActiveCare TD-4121 glucose meter and the ActiveCare TD-4121 blood glucose test strip.

The ActiveCare TD-4121 Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The ActiveCare TD-4121 Blood Glucose Monitoring System is not intended for the diagnosis of, or screening of diabetes. It is not intended for use on neonates.

5. Device Description

The ActiveCare TD-4121 Blood Glucose Monitoring System is comprised of the ActiveCare TD-4121 glucose meter and the ActiveCare TD-4121 blood glucose test strip. They have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only ActiveCare TD-4121 blood glucose test strip with ActiveCare TD-4121 Blood Glucose Monitoring System.

6. Comparison to the Predicate

The modified ActiveCare TD-4121 Blood Glucose Monitoring System has the following similarities and modifications to the predicate device:

Similarities	Modifications
1. Operating principle 2. Detection method and scientific technology 3. Employs the same test strip 4. Operation and storage conditions 5. Accuracy 6. Component materials 7. Packaging materials 8. Shelf life	1. Changed meter appearance and size 2. Change battery type from 2 pieces of 3V AAA batteries to 1 Li-polymer battery. 3. PCB layout change 4. Changed memory type from EEprom to FLASH 5. Revise the contents of user manuals and labeling

9. Manufacturing process	6. The user interface was modified from buttons to touchscreen 7. The Gen/AC/PC function was modified into 8 tags (before breakfast, after breakfast, before lunch, after lunch, before dinner, after dinner, general, QC) 8. Error messages are different from predicate 9. Removed transmission function

7. Test principle

The blood glucose is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter utilizes the current signal to calculate the blood glucose level.

8. Traceability

This system is compared to the YSI-2300 Glucose Analyzer in the clinical and non-clinical studies. The YSI is calibrated with NIST (SRM) 917A reference material.

9. Conclusion

Based on the information provided in this submission, the ActiveCare TD-4121 Blood Glucose Monitoring System and TD-4277 Blood Glucose Monitoring System are substantially equivalent.