June 4, 2019

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

Re: K190579
Trade/Device Name: TD-4183 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: February 27, 2019
Received: March 6, 2019

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 and Part 809); 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,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190579

Device Name
TD-4183 Blood Glucose Monitoring System

Indications for Use *(Describe)*
The TD-4183 Blood Glucose Monitoring System consists of the TD-4183 Blood Glucose meter and the TD-4183 Blood Glucose Test Strips.

The TD-4183 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. This system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of the diabetes control program. It is intended to be used by single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and 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

Submission Number: k190579

In accordance with the requirements of 21 CFR 807.92, this summary is being provided to serve as the basis for the substantial equivalence determination.

Submitter information

Manufacturer	TaiDoc Technology Corporation
Address	6F, No. 127, Wugong 2nd Rd. Wugu Dist. New Taipei City, Taiwan 24888
Establishment Registration No.	3004145393
Date Prepared	May 10, 2019
Correspondent	TaiDoc Technology Corporation
Correspondent Contact	Sophia Wu
Title	Regulatory Affairs Vice President
Phone	+886-2-6625-8188
E-mail	sophiawu@taidoc.com.tw

Proposed Device Information

Proprietary name	TD-4183 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	2
Regulation Number	21 CFR §862.1345

Predicate Device Information

Manufacturer	TaiDoc Technology Corporation
Proprietary Name	TD-4277 Blood Glucose Monitoring System
Common Name	Blood Glucose Monitoring System
510(k) Number	K100322

Intended use

The TD-4183 Blood Glucose Monitoring System consists of the TD-4183 Blood Glucose meter and the TD-4183 Blood Glucose Test Strips.

The TD-4183 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. This system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of the diabetes control program. It is intended to be used by single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Device Description

The TD-4183 system kit includes the TD-4183 Blood Glucose meter with blood glucose measuring function and the TD-4183 Blood Glucose test strips. This system is a single-patient use blood glucose monitoring system intended to be used to quantitatively measure glucose in fresh capillary whole blood from the finger as an aid in monitoring the effectiveness of glucose control.

Test principle

The blood sample is applied to the absorbent hole at the end of the test strip to fill the window. When the blood sample is absorbed into the test strip, the blood glucose reacts with the reagent contained in the test strip and generates electrical current. When the meter receives the signal through the connector, the signal is then transferred into calculated blood glucose level and displayed on the LCD screen. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Summary of Technological Characteristics and Comparison to the Predicate

The TD-4183 Blood Glucose Monitoring System is substantially equivalent to the predicate device in terms of technological characteristics.

The similarities and differences between the predicate and proposed devices are summarized in Table 1 and 2 below.

Table 1: Similarities between the Predicate and Proposed Device

Characteristic	Predicate device TD-4277	Proposed device TD-4183
Operation principle	Electrochemical biosensor technology	the same as the predicate device
Detection method	Amperometric glucose biosensor	the same as the predicate device
Mode of operation	User initiates test on meter, inserts test strip into meter, lances finger with lancing device, and places blood sample on test strip.	the same as the predicate device
Strip preparation	Strips are stored in a humidity-controlled vial (25-50 strips per vial), user removes one strip from vial and inserts in meter for testing.	the same as the predicate device
Code calibration	No coding required	the same as the predicate device
Strip enzyme	FAD Glucose dehydrogenase (*E. coli*)	the same as the predicate device
Strip reaction time	6 seconds	the same as the predicate device
Strip sample volume	0.5 μL	the same as the predicate device
Measurement unit	mg/dL	the same as the predicate device
Measurement modes	AC (before meal) PC (after meal) Gen (not specified) QC (quality control)	the same as the predicate device
User interface	LCD and buttons	the same as the predicate device
Display of test results	LCD screen	the same as the predicate device
Software design	Meter software controls the measurement and calculation of blood glucose and displays result on the meter.	the same as the predicate device

Table 2: Differences between the Predicate and Proposed Device

Characteristic	Predicate device TD-4277	Proposed device TD-4183
Physical Appearance		
Meter Size (mm)	96 (L) x 61 (W) x 26 (H)	90.3 (L) x 52.3 (W) x 18 (H)
Meter Weight (g)	67.2 g	46.8 g
Measurement range	20-600 mg/dL	20-650 mg/dL
Hematocrit range	20-60%	20-65%
Power source	2 x 1.5V AAA batteries	1 x 1.5V AAA batteries
Transmission function	USB	NA
Meter storage/ transportation condition	-4℉ to 140℉, < 95% R.H.	-4℉ to 140℉, 10% to 93% R.H.
Strip storage/ transportation condition	35.6℉ to 89.6℉, < 85% R.H.	35.6℉ to 86℉, 10% to 85% R.H.

Characteristic	Predicate device TD-4277	Proposed device TD-4183
Intended use	TD-4277 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. Professionals may use the test strips to test capillary and venous blood samples, but lay user may not test venous blood samples.	The TD-4183 Blood Glucose Monitoring System consists of the TD-4183 Blood Glucose meter and the TD-4183 Blood Glucose Test Strips. The TD-4183 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. This system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes mellitus at home as an aid in monitoring the effectiveness of the diabetes control program. It is intended to be used by single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Summary of Testing

Non-clinical and clinical studies were conducted to test, verify and validate the performance of the proposed device according to FDA Guidance issued on October 11, 2016: *Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use*. Results from these studies show that all performance criteria were met.

Non-Clinical Testing Summary: Design verification and validation testing was performed to ensure that the TD-4183 System met design specifications and requirements. Testing activities included electrical/mechanical safety tests, functional performance tests (precision, linearity, interference, flex studies) as well as disinfection, cleaning, and robustness studies. Software validation was performed for this moderate level of concern device per FDA Guidance *Content of Premarket Submissions for Software Contained in Medical Devices*.

Clinical Testing Summary: A user evaluation confirmed the system accuracy, operation according to design, and ease of use to support the intended use as described in the proposed labeling.

Conclusion

Based on the information provided in this submission, the TD-4183 Blood Glucose Monitoring System has been shown to be substantially equivalent to the TD-4277 Blood Glucose Monitoring System (K100322).