DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 14, 2017

TAIDOC TECHNOLOGY CORPORATION
PAUL LIU, REGULATORY AFFAIRS SPECIALIST
B1-7F, NO. 127, WUGONG 2ND RD.,
WUGU DISTRICT
NEW TAIPEI CITY 24888, TAIWAN

Re: K162382
Trade/Device Name: Smart Dongle Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JQP
Dated: February 23, 2017
Received: February 27, 2017

Dear Paul Liu:

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), 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,

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)*
k162382

Device Name
Smart Dongle Blood Glucose Monitoring System

Indications for Use *(Describe)*
The Smart Dongle Blood Glucose Monitoring System consists of the Smart Dongle meter, single use Smart Dongle test strips, and the Smart Dongle mobile application as the display component of the Smart Dongle Blood Glucose Monitoring System. The Smart Dongle Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger. This blood glucose monitoring system is intended to be used by a single person and should not be shared. Smart Dongle Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor 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: K162382

1. Submitter Information

Company Name:	TaiDoc Technology Corporation
Contact Person:	Paul Liu
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E-mail:	paul@taidoc.com.tw
Prepared Date:	Apr. 11th, 2016

2. Device name:

Proprietary Name:	Smart Dongle Blood Glucose Monitoring System
Common Name:	Blood Glucose Monitoring System
Product Code:	NBW, Blood Glucose Test System, Over-the-Counter LFR, Glucose Dehydrogenase JQP, Calculator/Data Processing Module
Classification Panel:	Clinical chemistry
Classification:	Class II Class I, exempt
Regulation Citation:	21 CFR §862.1345 21 CFR §862.2100

3. Predicate Device

U-RIGHT TD-4279 blood glucose monitoring system (k101509)

4. Intended Use

The Smart Dongle Blood Glucose Monitoring System consists of the Smart Dongle meter, single use Smart Dongle test strips, and the Smart Dongle mobile application as the display component of the Smart Dongle Blood Glucose Monitoring System. The Smart Dongle Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger. This blood glucose monitoring system is intended to be used by a single person and should not be shared. Smart Dongle Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. This system should not be used for the diagnosis of or screening for diabetes, nor for use on neonates.

5. Device Description:

The system consists of blood glucose meter, test strips and mobile platform (as a display of the system). And, the blood glucose meter is compatible to iPhone series, including iPhone 4, iPhone 4s, iPhone 5, iPhone 5s, iPhone 6, iPhone 6 plus, iPhone 6s and iPhone 6s plus. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Smart Dongle Blood Glucose Test Strips can be used only with the Smart Dongle Blood Glucose Monitoring System.

6. Comparison to the Predicate:

Item	Proposed device	Predicate device
Brand Name	**Smart Dongle Blood Glucose Monitoring System**	**U-RIGHT TD-4279 blood glucose monitoring system (k101509)**
Intended Use	In the quantitative measurement of glucose in fresh capillary whole blood from the finger	In the quantitative measurement of glucose in fresh capillary and venous whole blood
Assay method	**Same as Predicate**	Glucose dehydrogenase biosensor
Measuring range	**Same as Predicate**	20-600 mg/dL
Sample type	Capillary finger stick	Capillary finger stick and Venous whole blood
Sample size	1.0 uL	1.1 uL
Hematocrit range	**Same as Predicate**	20 % – 70 %
Analysis time	**Same as Predicate**	5 sec

Coding	No coding	Code strip
Operating conditions	**Same as Predicate**	10 ℃ – 40 ℃, 10% – 85% R.H.
Power source	Powered by mobile platform	Two AAA batteries
Display	Displayed on mobile platform: iPhone 4, iPhone 4s, iPhone 5, iPhone 5s, iPhone 6, iPhone 6 plus, iPhone 6s, iPhone 6s plus and iPod touch 5th generation	LCD display
Data storage	Results stored in the mobile platform	Results stored in the device
Data transmission	Headphone port jack	Data cable

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. Performance Characteristics:

Clinical and non-clinical studies were conducted to tested, verified and validated with respect to the predicate device to establish the performance of the Smart Blood Glucose Monitoring System. The data demonstrates that the Smart Dongle Blood Glucose Monitoring System is substantially equivalent to the predicate devices.

Accuracy

Results for glucose concentration <75 mg/dL

Within 5 mg/dL	Within 10 mg/dL	Within 15 mg/dL
42% (21/50)	98% (49/50)	100% (50/50)

Results for glucose concentration ≧75 mg/dL

Within 5%	Within 10 %	Within 15 %	Within 20 %
57/110 (51.8%)	105/110 (95.5%)	110/110 (100%)	110/110 (100%)

Precision

Intermediate precision

Control solutions	Level 1	Level 2	Level 3
Mean (mg/dL)	49.6	139.4	335.4
SD (mg/dL)	2.17	4.37	10.10
CV (%)	4.38%	3.13%	3.01%

Repeatability

Blood samples	Level 1	Level 2	Level 3	Level 4	Level 5
Mean (mg/dL)	49.7	91.2	128.3	227.8	390.2
SD (mg/dL)	2.18	2.95	4.06	7.18	12.06
CV (%)	4.39%	3.23%	3.16%	3.15%	3.09%

9. Conclusion:

Based on the information provided in this submission, the Smart Dongle Blood Glucose Monitoring System is substantially equivalent to the predicate (k101509).

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