November 30, 2018

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

Re: K181588
Trade/Device Name: POPS! one Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: October 26, 2018
Received: October 31, 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. 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/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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181588

Device Name
POPS!® one Blood Glucose Monitoring System

Indications for Use *(Describe)*
The POPS!® one Blood Glucose Monitoring System is comprised of the POPS!® one blood glucose meter, the POPS!® one blood glucose sensor modules, and the POPS!® mobile application as the display component.

The POPS!® one 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 POPS!® one Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It 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

Assigned 510(k) number: **K181588**

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

Submitter information

Manufacturer	TaiDoc Technology Corporation
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Establishment Registration No.	3004145393
Date Prepared	November 30, 2018
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Proposed Device Information

Proprietary name	POPS!® one 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

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 POPS!® one Blood Glucose Monitoring System is comprised of the POPS!® one blood glucose meter, the POPS!® one blood glucose sensor modules, and the POPS!® mobile application as the display component.

The POPS!® one 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 POPS!® one Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It is not intended for the diagnosis of, or screening of diabetes. It is not intended for use on neonates.

Device Description

The POPS!® one Blood Glucose Monitoring System is designed to make blood glucose testing and diabetes management easier and more convenient. The traditional test kit is replaced by a low-profile meter that contains everything needed for testing and requires no assembly. The meter pairs with a mobile app installed on the user's phone via Bluetooth, allowing the meter to perform glucose testing and send the results to the app where they are communicated to the user and automatically stored.

The POPS!® one Blood Glucose Monitoring System contains the following:

- **POPS!® one blood glucose meter** works directly with the POPS!® app installed on the user's mobile phone. The meter performs a blood glucose test and sends the result to the POPS!® app.
- **POPS!® one blood glucose sensor module** is individually packed and sterile. It contains 3 test sites with separate foil covers; each containing a lancet and test strip. The user inserts the sensor module in the meter and replaces a used sensor module with a new one once all 3 test sites have

been used. The sensor module not only provides all components for performing a glucose test to the user in a convenient, self-contained format but it also provides a new lancet for each test; preventing lancet re-use.

- **POPS!® mobile application** acts as the primary interface with users; enabling them to test, communicating blood glucose results and messages, and allowing them to monitor trends on their phone.

Test principle

The blood glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip within the Sensor Module. The system measures the current, calculates the blood glucose level, and displays the result. 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 POPS!® one Blood Glucose Monitoring System is substantially equivalent to the predicate device, both in terms of intended use and technological characteristics. The primary differences between the proposed and predicate device are design changes to simplify the glucose testing experience and allow communication of results and messages to the user to occur via the POPS!® app.

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 Devices

Characteristic	Predicate device TD-4277	Proposed device POPS!® one
Operation principle	Electrochemical biosensor technology	Electrochemical biosensor technology
Detection method	Amperometric glucose biosensor	Amperometric glucose biosensor
Code calibration	No coding required	No coding required
Enzyme	Glucose dehydrogenase	Glucose dehydrogenase
Strip reaction time	6 seconds	6 seconds
Sample volume	0.5 µL	0.5 µL

Characteristic	Predicate device TD-4277	Proposed device POPS!® one
Measurement range	20~600 mg/dL	20~600 mg/dL
Hematocrit range	20~60%	20~60%
Measurement unit	mg/dL	mg/dL
Measurement modes	Test Mode AC (before meal) PC (after meal) Gen (not specified) QC (quality control)	Test Mode AC (before meal) PC (after meal) Gen (not specified) QC (quality control)
Strip indication light	Yes	Yes
Meter storage/ transportation condition	-4℉ to 140℉, < 95% R.H.	-4℉ to 140℉, < 95% R.H.
Strip storage/ transportation condition	35.6℉ to 89.6℉, < 85% R.H.	35.6℉ to 89.6℉, < 85% R.H.

Table 2: Differences between the Predicate and Proposed Devices

Characteristic	Predicate device TD-4277	Proposed device POPS!® one
Physical Appearance		

Characteristic	Predicate device TD-4277	Proposed device POPS!® one
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 POPS!® one 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 POPS!® one Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It is not intended for the diagnosis of, or screening of diabetes. It is not intended for use on neonates.
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. If test result tracking is desired, user must do so manually.	User initiates test within app, lances finger with integrated lancet and places blood sample on the test strip. Recording of test results is done wirelessly and automatically in the app.

Characteristic	Predicate device TD-4277	Proposed device POPS!® one
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.	Individual strips are sealed in the sensor module with a foil seal to control humidity. User peels back the foil seal for the test site prior to testing, keeping the other strips covered/secure until use. This improves storage integrity of strips and minimizes user interaction with strips.
Lancet	Lancet in lancing device is changed out by user resulting in frequent re-use of lancets (increased infection risk and callous formation).	A new sterile lancet is provided in the sensor module with each test site, so users have a new lancet for each test.
Software design	Meter software controls the measurement and calculation of blood glucose and displays result on the meter.	Meter software controls the measurement and calculation of blood glucose and transmits the information to the POPS!® app for display and storage of results.
Meter Size (mm)	96 (L) x 61 (W) x 26 (H)	43 (L) x 39 (W) x 24 (H)
Meter Weight (g)	67.2 g	13 g
Power source	2 x 1.5V AAA batteries	1 CR2032 battery
User interface	LCD and buttons	Mobile application
Display of test results	LCD screen	Mobile application
Transmission function	USB	Encrypted and secure Bluetooth
Error messages	Error number displayed on LCD screen	Error number translated into text and displayed on App
PCB layout	circuit designed for one test site	circuit designed for three test sites

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 POPS!® one 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, robustness, sterilization, shelf life and transit 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 POPS!® one Blood Glucose Monitoring System has been shown to be substantially equivalent.to the TD-4277 Blood Glucose Monitoring System.