**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

k181588

**B. Purpose for Submission:**

New device

**C. Measurand:**

Glucose in fresh capillary whole blood samples obtained from the fingertip

**D. Type of Test:**

Quantitative, electrochemical method, glucose dehydrogenase

**E. Applicant:**

TaiDoc Technology Corporation

**F. Proprietary and Established Names:**

POPS!® one Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:

   21 CFR 862.1345, Glucose test system

2. Classification:

   Class II

3. Product code:

   NBW – System, Test, Blood Glucose, Over The Counter

4. Panel:

   Chemistry (75)

## H. Intended Use:

1. Intended use(s):

   See indication(s) for use below.

2. Indication(s) for 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.

3. Special conditions for use statement(s):

   - This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
   - Should not be used for the diagnosis of, or screening for diabetes
   - For single-patient use only
   - Each sensor module test site (lancet and strip) is for single use only
   - For self-testing
   - Severe dehydration and excessive water loss may cause inaccurate readings.
   - This device is limited for use with fresh capillary whole blood from the fingertip and should not be used for alternative site testing (i.e. palm, forearm, thigh etc.).
   - Altitudes above 15,000 feet may cause inaccurate results.
   - Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hypoglycemic hyperosmolar state, with or without ketosis.

- This system is not for use in patients with abnormally low blood pressure or those who are in shock.
- This system is not for use with neonates.
- This system should not be used on critically ill patients.

4. Special instrument requirements:

   POPS! blood glucose meter

   iPhone (5, 5S, 5C, 6, 6 plus, 6S, 6S plus, 7, 7 plus, 8, 8 plus, with iOS 10+ or 11+) with the POPS! app installed

## I. Device Description:

The POPS! one Blood Glucose Monitoring System consists of 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. Each sensor module contains 3 test sites with separate foil covers, each containing a lancet and test strip. . The Sensor Modules come with four lance levels to give blood drops of different sizes (level 1 = smallest drop, level 4 = largest drop).

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

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   TD-4277 Blood Glucose Monitoring System; TaiDoc Technology Corporation

2. Predicate 510(k) number(s):

   k100322

3. Comparison with predicate:

| Characteristic | Candidate Device<br>POPS! one Blood Glucose Monitoring System<br>k181588 | Predicate Device<br>TD-4277 Blood Glucose Monitoring System<br>k100322 |
|---|---|---|
| Similarities | | |
| Intended use | Intended for the quantitative measurement of glucose in fresh capillary blood samples by people with diabetes at home to aid in monitoring the effectiveness of diabetes control. | Same |
| Intended use population | Single-patient use | Same |
| Detection method | Amperometric glucose biosensor | Same |
| Methodology | Glucose dehydrogenase | Same |
| Code calibration | No coding required | Same |
| Strip reaction time | 6 seconds | Same |
| Sample volume | 0.5 µL | Same |
| Measurement range | 20-600 mg/dL | Same |
| Hematocrit range | 20-60% | Same |
| Differences | | |
| User interface | Mobile application | LCD and buttons |
| Display of test results | Mobile application | LCD screen |
| Transmission function | Encrypted and secure Bluetooth | USB |

**K. Standard/Guidance Document Referenced (if applicable):**

Guidance for Industry and Food and Drug Administration Staff, 2016. Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use

CLSI EP5-A2: 2004, Evaluation of Precision Performance of Quantitative Measurement Methods Approved Guideline

CLSI EP6-A, 1986. Evaluation of the linearity of quantitative analytical Methods; Proposed Guideline

CLSI EP7-A2: 2005, Interference Testing in Clinical Chemistry, Approved Guideline

IEC 61010-1, Edition 3.0: 2010, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements.

IEC 60601-1-2, Edition 3.0: 2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

## L. 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. The final results are communicated to the smart mobile device through a mobile application.

## M. Performance Characteristics (if/when applicable):

1. Analytical performance:

*a. Precision/Reproducibility:*

The sponsor performed repeatability (within-day) studies using venous whole blood samples adjusted to five different glucose concentrations (approximately 49, 106, 143, 246 and 392 mg/dL). Each glucose level was analyzed in replicates of ten, using sensor modules with test strips from three lots and ten meters for a total of 100 tests per each glucose level. Results are summarized below:

Repeatability precision summary:

| Glucose Level (mg/dL) | Mean (mg/dL) | SD (mg/dL) | % CV |
|---|---|---|---|
| 30 - 50 | 48.6 | 2.0 | 4.1 |
| 51 - 110 | 105.5 | 3.3 | 3.1 |
| 111 - 150 | 143.4 | 4.2 | 2.9 |
| 151 - 250 | 245.7 | 7.0 | 2.9 |
| 251 - 400 | 391.7 | 11.2 | 2.8 |

Intermediate precision was evaluated over 10 days using five levels of glucose control solutions with glucose concentrations of approximately 50, 95, 135, 245 and 309 mg/dL. Each sample was measured ten times using sensor modules with test strips from three lots and ten POPS! one meters. These tests were performed over ten days, for a total of 100 tests per glucose level. Results are summarized below.

Intermediate precision summary:

| Glucose Level (mg/dL) | Mean (mg/dL | SD (mg/dL) | % CV |
|---|---|---|---|
| 30 - 50 | 49.7 | 2.1 | 4.1 |
| 51 - 110 | 95.2 | 3.5 | 3.7 |
| 111 - 150 | 134.7 | 4.1 | 3.0 |
| 151 - 250 | 245.0 | 7.5 | 3.1 |
| 251 - 400 | 308.8 | 8.2 | 2.7 |

*b. Linearity/assay reportable range:*

Linearity was evaluated using sensor modules with test strips from three lots and 11 mixed pools of venous whole blood samples with glucose concentrations of approximately 17, 41, 59, 101, 145, 187, 279, 388, 429, 521 and 622 mg/dL as measured by YSI 2300. Each level was measured in replicates of 15 and the values from the POPS! one meters were compared with those obtained from YSI 2300. Linear regression analysis of the results yielded the following:

Lot 1: $y = 1.008x - 0.076$ $R^2 = 0.998$
Lot 2: $y = 1.002x + 0.599$ $R^2 = 0.998$
Lot 3: $y = 1.004x + 0.541$ $R^2 = 0.997$

The results of the study support the sponsor's claimed glucose measurement range of 20-600 mg/dL. If a sample is less than 20 mg/dL glucose, the meter's mobile application will display the error message "Your result was less than 20 mg/dL, which is lower than the measuring range of the meter". If a sample exceeds 600 mg/dL glucose, the meter's mobile application will display the error message: "Your result was greater than 20 mg/dL, which is higher than the measuring range of the meter". These low and high functions were validated and demonstrated to function as intended.

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability

The POPS! one Blood Glucose Monitoring System is traceable to NIST SRM # 917c glucose reference material.

Sensor module stability:
The stability of the POPS! one sensor module was assessed using accelerated and real-time studies. The testing protocols and acceptance criteria were reviewed and found to be acceptable to support the manufacturer's labeled claims for a shelf life stability of 6 months for a sealed package (sensor module in foil

packaging) and 5 days for an opened package (sensor module outside of the foil package) at the recommended storage temperatures of 35.6°F-86°F (2°C-30°C) and 10-90% relative humidity.

*d. Detection limit:*

The reportable range is 20 to 600 mg/dL based on linearity studies above.

*e. Analytical specificity:*

Interference studies were performed by spiking venous whole blood to achieve three glucose levels (50 -70 mg/dL, 110 –130 mg/dL and 225 -270 mg/dL). Each of these samples was divided into a test sample with the potential interferent added and a control sample with no added interferent. Each sample was measured using ten meters and sensor modules with test strips from three lots, for a total of 30 replicates per sample. Results on the candidate meter from the test samples were compared to results on the candidate meter from the control sample. No interference was defined by the sponsor as ≤ 10% bias at each glucose level. The highest concentrations at which no significant interference was observed are presented in the following table:

| **Potential Interfering Substance** | **Maximum Concentration with no Significant Interference (mg/dL)** |
|---|---|
| Acetaminophen | 6.25 |
| Ascorbic Acid | 5.0 |
| Bilirubin (conjugated) | 30 |
| Bilirubin (unconjugated) | 20 |
| Cholesterol | 500 |
| Creatinine | 30 |
| Dopamine | 1.25 |
| $Na_4EDTA$ | 400 |
| Hemoglobin | 14700 |
| Heparin (Na) | 790 |
| Ibuprofen (sodium) | 55 |
| Icodextrin | 2000 |
| Levo-Dopa | 0.7 |
| Maltose | 1000 |
| Methyl-Dopa | 1.875 |
| Na-Fluoride | 200 |
| Gentisic Acid | 4 |
| Pralidoxime Iodide | 5 |
| Reduced Glutathione | 30 |
| Salicylic acid | 60 |
| Sodium (NaCl) | 460 |
| Sugar alcohols* | 1000 |
| Tolazamide | 12.5 |

| | |
|---|---|
| Tolbutamide | 100 |
| Triglycerides | 3000 |
| Xylose | 3.125 |

*Sugar alcohols tested: isomalt, lactitol, maltitol, sorbitol, xylitol.

Based on the test restuls, the sponsor has included the following statements in the labeling:

- If you have a disease or condition in which uric acid levels in your blood may be elevated (> 10 mg/dL), such as gout, you may get inaccurate results with this system. If you are unsure, then ask your health care professional.
- Acetaminophen in your blood (> 6.25 mg/dL) might affect the reliability of your blood glucose results. If you are taking Tylenol, or other acetaminophen containing drugs, your glucose results may not be reliable. If you are unsure, then ask your health care professional.
- Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

See M.3.c below.

*b. Matrix comparison:*

Not applicable.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable.

*b. Clinical specificity:*

Not applicable.

*c. Other clinical supportive data (when a. and b. are not applicable):*

To assess the performance of the POPS! one Blood Glucose Monitoring System (TD-4142) in the hands of the intended users, the sponsor performed a study with 362 English speaking participants. The users were responsible for obtaining their own

fingertip capillary sample and performing a blood glucose test using only the instructions from the product labeling. A total of 362 POPS! meters, three lots of sensor modules and 6 iPhones (model 6,6,7, 7 plus and 8) were used. Results were analyzed by comparing the blood glucose results obtained by the lay users with the POPS! one Blood Glucose Monitoring System against results obtained with a laboratory-based comparator method (YSI 2300 analyzer). The glucose concentrations in the samples ranged from 53-553 mg/dL, as measured by the YSI 2300. The results are summarized below:

For glucose concentrations < 75 mg/dL:

| **Within ± 5 mg/dL** | **Within ±10 mg/dL** | **Within ± 15 mg/dL** |
|---|---|---|
| 63.6% (7/11) | 100% (11/11) | 100% (11/11) |

For glucose concentrations ≥ 75 mg/dL:

| **Within ± 5%** | **Within ± 10%** | **Within ± 15%** | **Within ± 20%** |
|---|---|---|---|
| 55.3% (194/351) | 84.6% (297/351) | 97.7% (343/351) | 99.7% (350/351) |

Combined glucose concentrations across the measuring range:

| **Within ± 5%** | **Within ± 10%** | **Within ± 15%** | **Within ± 20%** |
|---|---|---|---|
| 55.0% (199/362) | 84.0% (304/362) | 97.8% (354/362) | 99.7% (361/362) |

Results of linear regression analysis: $y = 0.96 x + 5.61$, $R^2 = 0.96$

Accuracy at Extreme Glucose Values:

A study to evaluate the performance of POPS! one Blood Glucose Monitoring System in the extreme upper and lower ends of the claimed measuring range was performed using 50 altered samples with glucose concentrations below 80 mg/dL and 50 samples greater than 250 mg/dL. Samples were altered by spiking or glycolysis in order to obtain the appropriate glucose concentrations. Samples were tested in replicates of six using two POPS! one meters and sensor modules with test strips from three lots, and compared to the average of two YSI 2300 measurements.

For glucose concentrations < 80 mg/dL:

| **Within ± 5 mg/dL** | **Within ±10 mg/dL** | **Within ± 15 mg/dL** |
|---|---|---|
| 84.7% (254/300) | 99.3% (298/300) | 100% (300/300) |

For glucose concentrations > 250 mg/dL:

| **Within ± 5%** | **Within ± 10%** | **Within ± 15%** | **Within ± 20%** |
|---|---|---|---|
| 50.3% (151/300) | 85.3% (256/300) | 98.3% (295/300) | 100% (100/100) |

Readability:
Flesch-Kincaid readability assessment was conducted and the results demonstrated that the User Manual, quick start guide, test strip package insert and control solution package insert were written at an 8th grade level or less.

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   The POPS! one Blood Glucose Monitoring System provides plasma equivalent results. Expected plasma glucose values for people without diabetes:

| **Time of day** | **Range** |
|---|---|
| Fasting and before meals | < 100 mg/dL |
| 2 hours after meals | < 140 mg/dL |

   Source: American Diabetes Association. Standards of medical care in diabetes 2018; Diabetes Care, vol. 41, supplement 1.

**N. Instrument Name:**

POPS!® one Blood Glucose Meter with the POPS mobile application

**O. System Descriptions:**

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ____X____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ____X____ or No _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ____X____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The meter does not require calibration or coding by the user. The meters are automatically coded.

6. Quality Control:

   Only one control solution (W2) is provided with the meter. Additional control solutions levels (B3) may be ordered through customer service. Recommendations on when to perform a control solution test are provided in the labeling, and an acceptable range is printed on the sensor module box. The user is cautioned not to use the meter and to contact customer support if the test results falls outside this range.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**

1) Hematocrit Study:
   To evaluate the effect of hematocrit on the POPS! one Glucose Monitoring System, venous whole blood samples were adjusted to hematocrit levels of 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55% and 60%. Each hematocrit level was adjusted to achieve five concentrations within the following ranges: 30-50, 51-110, 111-150, 151-250 and 251-400 mg/dL. Each sample was then tested using 10 POPS! one meters and sensor modules with test strips from 3 lots. The values were compared with the average of 4 glucose measurements obtained from YSI 2300 analyzer. The % biases relative to the comparator method were acceptable within the claimed hematocrit range of 20% to 60%.

2) Altitude study:
   To evaluate the effect of altitude on blood glucose measurement of POPS! one Blood Glucose Monitoring System, a study was conducted using venous whole blood samples adjusted with 7 concentration levels of glucose ranging from 51 to 600 mg/dL. Samples were placed under conditions to simulate 4 different altitude conditions from sea level to 4500 meters (15,000 feet). Each blood sample was tested using 4 POPS! one meters and one lot of sensor modules; the values were compared with the values obtained with the YSI 2300 analyzer outside of the pressurized chamber. The results demonstrate acceptable bias to YSI 2300 to support the claims in the labeling that glucose

measurement performance of the POPS! one System is maintained at altitudes ranging from the sea level up to 4,500 meters (15,000 feet).

3) Operating conditions:
The effect of temperature and relative humidity on the POPS! Blood Glucose Monitoring System was evaluated using venous whole blood samples adjusted to approximately 65 mg/dL, 125 mg/dL, and 320 mg/dL glucose. Testing was conducted under the following temperature and relative humidity (RH) combinations: 8°C (46.4°F) and 42°C (107.6°F) at 10% and 90% RH each and at 25°C (77°F) at 60% RH. Four POPS! one meters and three lots of test strips were used. Values measured by the POPS! one glucose meters were compared to results from the comparator method YSI 2300. The study results support the operating condition claim of 50 to 104°F (10 to 40°C) with relative humidity of 15% to 85%.

4) Sample volume study:
The sponsor performed a study to support the claimed minimum sample volume for the POPS! one system. Venous whole blood samples with three levels of glucose concentrations (50-65, 100-120, and 200-250 mg/dL) were tested at six sample volumes (0.3, 0.4, 0.5, 0.6, 0.7 and 0.8, µL) using 3 lots of test strips and 10 meters. Values obtained were compared to YSI 2300 values. The meter has an error message that is displayed on the mobile application when not enough blood is added to the test strip. This feature was validated and was shown to function as intended. Results support the claimed minimum sample volume of 0.5 µL.

5) Sample perturbation study:
The sponsor performed sample perturbation studies using venous whole blood samples comparing meter readings to YSI 2300 results. Results were obtained without perturbation of the test strip and with perturbation. The results demonstrate that the performance of POPS! one Blood Glucose Monitoring System is not affected by perturbed sample.

6) Intermittent sampling
The sponsor assessed the performance of the device when intermittent sampling occurs using venous whole blood samples comparing meter readings to results from the comparator method YSI 2300. Results were obtained by adding samples to the test strip that were less than the required volume followed by a second sample application to the test strip. The results demonstrate that the performance of POPS! one Blood Glucose Monitoring System is not affected by intermittent sampling.

7) Testing with used test strips
The sponsor assessed the performance of the device when used test strips were inserted into the meter . Each test resulted in an error message displayed on the mobile application. The results demonstrate that the error code functions as intended when used test strips are used.

8) Infection Control:
The device is intended for single-patient use only. Disinfection efficacy studies were performed on the meter materials by an outside commercial laboratory, demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant Micro-Kill+™ Disinfecting Wipes (EPA Registration Number 59894-10-37549). Robustness studies were also performed by the sponsor using the POPS! one Blood Glucose Monitoring System and demonstrating that there was no change in the performance of the system or in the internal and external materials of the meter after 260 cycles of cleaning and disinfection cycles, using the chosen disinfectant, to simulate cleaning and disinfecting the meter once per week over the expected service life of 5 years for a single-patient use glucose meter. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

9) A variety of mechanical and durability tests (i.e., drop, vibration, shipping) were performed demonstrating that the meter is robust to environmental and mechanical stresses.

10) Electrical Safety and EMC testing
The sponsor provided documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed and the system was found to be compliant.

11) The test strip and sensor module lot release protocols and criteria were reviewed and found to be acceptable.

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.