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

A. 510(k) Number:
k162382

B. Purpose for Submission:
New device

C. Measurand:
Glucose in fresh capillary whole blood

D. Type of Test:
Quantitative, Amperometric method, glucose dehydrogenase (GDH-FAD)

E. Applicant:
TaiDoc Technology Corporation

F. Proprietary and Established Names:
Smart Dongle Blood Glucose Monitoring System

G. Regulatory Information:

Regulation Section	Classification	Product Code	Panel
21 CFR 862.1345	Class II	LFR, Glucose Dehydrogenase	Clinical Chemistry (75)
21 CFR 862.1345	Class II	NBW, System, Test, Blood Glucose, Over the Counter	Clinical Chemistry (75)
21 CFR 862.2100	Class I limitations of exemption 862.9(c)(5)	JQP, Calculator/Data Processing Module, For Clinical Use	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for 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.

3. Special conditions for use statement(s):
   - Not for the screening or diagnosis of diabetes mellitus
   - Severe dehydration and excessive water loss may cause inaccurate readings
   - Do NOT use the Smart Dongle Blood Glucose Monitoring System on severely hypotensive individuals or patients in shock
   - Do NOT use the Smart Dongle Blood Glucose Monitoring System on neonates, patients who are critically ill or patients in hyperglycemic-hyperosmolar state, with or without ketosis
   - For in vitro diagnostic use only
   - Do not reuse the strip
   - The meter and lancing device are for single patient use. Do not share them with anyone including other family members. Do not use on multiple patients.
   - This system is not for use in patients with abnormally low blood pressure or those who are in shock.
   - This system should not be used on patients with impaired peripheral circulation

4. Special instrument requirements:
   - Smart Dongle Meter
   - Smart Dongle App
   - Apple iPhone 4, 4s, 5, 5s, 6, 6+, 6s+, or Apple iPod touch 5th generation
   - Apple iOS version 7, 8, 9

I. Device Description:

Smart Dongle Blood Glucose Monitoring System is sold as one of two kit configurations:

Version with test strips:
- A glucose meter
- Protective plastic sleeves (for iPhone)
- Test strips

Version without test strips:
- A glucose meter
- Protective plastic sleeves

The system uses FORA control solutions (three concentrations: Level 1, 2, and 3) that were previously cleared in k093724 and are provided separately from the device.

This system measures the concentration of glucose in blood with an amperometric glucose biosensor embedded in the meter, that measures the volume of electrical signal generated by the reaction of glucose in blood sample with the metabolizing enzyme system (glucose dehydrogenase) implanted on test strip, and then translates into glucose concentration and thereafter is transmitted to and displayed on the screen of iPhone via earphone jack. Test results will show on the screen after 5 seconds reaction time. The proposed device does not need a battery, and is powered by the smartphone. It stores one measurement, while all the data are stored in the smartphone.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   U-RIGHT TD-4279 Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k101509

3. Comparison with predicate:

Similarities and Differences		
Item	**Candidate Device (Smart Dongle BGMS, k162382)**	**Predicate Device (U-RIGHT TD-4279 Blood Glucose Monitoring System, k101509)**
Intended Use	Intended for the quantitative measurement of glucose in fresh capillary blood samples by people with diabetes at home to monitor the effectiveness of diabetes control	Same
Assay Method	Glucose dehydrogenase	Same
Measuring Range	20-600 mg/dL	Same
Sample Type	Capillary fingerstick	Capillary fingerstick and venous whole blood
Sample size	1.0 µL	1.1 µL
Hematocrit range	20-70%	Same
Operating Conditions	10-40°C and 10-85% RH	Same
Data Storage	Results stored by mobile platform	Results stored in device
Display	Connect to iOS device to display results	LCD display

Similarities and Differences		
Item	**Candidate Device (Smart Dongle BGMS, k162382)**	**Predicate Device (U-RIGHT TD-4279 Blood Glucose Monitoring System, k101509)**
Data transmission	Earphone Jack	Data cable
Analysis Time	5s	Same
Power Source	Powered by iOS device connected to the meter	Two AAA batteries
Coding	No coding	Code strip

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

- CLSI-EP05-A2 Evaluation of precision performance of quantitative measurement methods
- CLSI-EP07-A2 Interference testing in clinical chemistry
- IEC 60601-1-2 Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests

L. Test Principle:

This system measures the concentration of glucose in blood with an amperometric glucose biosensor embedded in the meter, that measures the volume of electrical signal generated by the reaction of glucose in blood sample with the metabolizing enzyme system (glucose dehydrogenase) implanted on test strip, and then translates into glucose concentration and thereafter is transmitted to and displayed on the screen of iPhone or iPad via earphone jack. Test results will show on the screen after 5 seconds reaction time

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Intermediate Precision (Reproducibility)

   Intermediate precision was evaluated using three levels of control solutions: 30-50 mg/dL, 96 to 144 mg/dL, and 280 to 420 mg/dL. Three strip lots and ten Smart Dongle meters were evaluated over a total of ten days (total of 300 measurements). For each test strip lot, each sample was tested ten times per day over the ten day period. The mean values and coefficients of variation calculated for each sample are summarized below.

Glucose level (mg/dL)	Test Strip Lot	n	Mean Meter Reading (mg/dL)	SD (mg/dL)	% CV	Overall Mean	Overall SD	Overall % CV
30-50 mg/dL (Level 1)	1	100	49.6	2.21	4.45%	49.6	2.17	4.38%
	2	100	49.4	2.17	4.40%			
	3	100	49.8	2.19	4.40%			
96-144 mg/dL (Level 2)	1	100	138.6	4.38	3.16	139.4	4.37	3.13
	2	100	140.0	4.21	3.01			
	3	100	139.5	4.48	3.21			
280-420mg/dL (Level 3)	1	100	336.6	10.16	3.02	335.4	10.10	3.01
	2	100	335.6	10.27	3.06			
	3	100	334.4	10.08	3.01			

Repeatability

Repeatability (within-run) precision was evaluated using venous whole blood spiked with high concentration dextrose solution (20,000 mg/dL). Five glucose concentrations ranges were prepared (30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL). Three test strip lots and 10 meters were used for this study. For each test strip lot, each sample was tested ten times with each meter. The mean values and coefficients of variation calculated for each sample are summarized below.

Glucose level (mg/dL)	Test Strip Lot	YSI Plasma (mg/dL)	n	Mean Meter Reading (mg/dL)	SD (mg/dL)	%CV
30-50	1	48.4	100	49.6	2.13	4.29
	2			49.9	2.21	4.43
	3			49.6	2.24	4.52
51-110	1	93	100	91.7	2.97	3.24
	2			91.2	3.04	3.34
	3			90.9	2.89	3.18
111-150	1	125	100	128.0	3.95	3.09
	2			128.3	4.07	3.17
	3			128.5	4.21	3.27
151-250	1	225	100	227.5	7.06	3.10
	2			229.0	7.36	3.21
	3			227.2	7.21	3.17
251-400	1	386	100	390.8	12.32	3.15
	2			390.2	12.06	3.09
	3			389.8	12.14	3.12

b. *Linearity/assay reportable range:*

Linearity was evaluated using venous blood drawn from healthy donors. The blood was allowed to stand at room temperature to glycolyze. The venous blood was spiked with concentrated D-Dextrose solution (~20,000 mg/dL) to achieve ten concentrations covering the range of glucose concentrations below and above 20-600 mg/dL (8, 43, 75, 116, 183, 291, 383, 469, 599, 758 mg/dL). Three lots of test strips and five blood glucose meters were used. Each level was tested in replicates of five with each of three test strip lots, resulting in a total of 15 replicates for each glucose level. The values from the Smart Dong bnmnnnle were compared to a laboratory-based comparator method (YSI 2300). The results from regression analysis are summarized below:

Lot 1: $y = 1.0008x+1.3651$, $R^2 = 0.9981$
Lot 1: $y = 1.0018x+0.7997$, $R^2 = 0.998$
Lot 1: $y = 1.0037x+1.2707$, $R^2 = 0.9978$

The sponsor's claimed glucose measurement range is 20 to 600 mg/dL.

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

Test strip closed vial stability:
Stability protocols and acceptance criteria were reviewed and found to be acceptable to support a shelf life of 25 months when stored at a temperature ranging from 36°F-86°F (2°C to 30°C) and between 10%-85% relative humidity.

Test strip open vial stability:
Stability protocols and acceptance criteria were reviewed and found to be acceptable to support an open-vial use life of three months at a temperature ranging from 36°F-86°F (2°C to 30°C) and between 10%-85% relative humidity.

Control Solution Stability:
Protocol and acceptance criteria were reviewed in k093724. The sponsor claims that the control solution is stable when unopened for two years (24 months) at the recommended storage temperature (36-86°F). The control solution is stable when opened for three months (90 days) at the recommended storage temperature (36-86°F).

Traceability:
The Smart Dongle Blood Glucose Monitoring 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.

d. *Detection limit:*

The reportable range for the Taidoc Smart Dongle is 20-600 mg/dL. This range was verified by the linearity study (M.1.b). The meter displays "LO" with glucose values

below 20mg/dL, and "HI" with glucose values over 600 mg/dL.

e. *Analytical specificity:*

Eighty-eight potential interfering substances consisting of exogenous substances (substances originating from outside the body such as therapeutic agents or vitamins) of the most commonly used critical care drugs endogenous substances (substances produced or originating from within the body), and common anticoagulants including heparin and Fluoride/Oxalate were screened for interference. Four Smart Dongle meters and four test strip lots were tested. Interference was screened by spiking each substance into a venous whole blood sample using highly concentrated dextrose (~20,000 mg/dL) to a concentration of either approximately 75 mg/dL or170 mg/dL. The sponsor defined no significant interference as bias within ±10%.

	Potential Interferent	Highest level without interference (mg/dL)
1	Acetylsalicylic Acid	50
2	Acetaminophen	6.25
3	Acyclovir	3.1
4	Allopurinol	5
5	Amitriptylline	0.27
6	Amoxicillin	12.5
7	Ampicillin	5
8	Ascorbic acid	5
9	Atenolol	10
10	Bicarbonate	336 (40 mM)
11	Bile Acids (Cholic Acid)	6
12	Bilirubin (Unconjugated)	20
13	Caffeine	10
14	Calcium	5 mM
15	Ceftriaxone	250
16	Chloride	140 mM
17	Cholesterol	500
18	Clonidine	2
19	Creatinine	5
20	Digoxin	0.16
21	Diphenhydramine	1
22	Dopamine	1.25
23	Enalapril	0.15
24	Ephedrine	50
25	Erythromycin	20
26	Estrone	0.1

	Potential Interferent	Highest level without interference (mg/dL)
27	Famotidine	0.13
28	Fluoxetine	0.8
29	Folic	13.3
30	Fructose	1000
31	Furosemide	2
32	Galactose	1000
33	Gentisic	2
34	Glutathione, reduced	30
35	Glyburide	1.07
36	Glycerol	1000
37	Hemoglobin	500
38	Ibuprofen	55
39	Icodextrin	2000
40	Isomalt	1000
41	Lactose	1000
42	Lactitol	1000
43	L-Dopa	0.7
44	Lidocaine	6
45	Lipemic Samples (Triglycerides)	>3000
46	Magnesium	5 mM
47	Maltitol	1000
48	Maltose	1000
49	Mannitol	5000
50	Mannose	250
51	Metaproterenol	1.81
52	Methyl-Dopa	0.625
53	Metformin	50
54	Metoprolol	0.3
55	Naproxen	100
56	Nifedipine	0.17
57	Nortriptyline	0.15
58	Penicillin	12
59	pH value	6.85-10.35
60	Phenytoin	10
61	Piroxicam	5
62	Potassium	10 mM
63	Pralidoxime Iodide	>5
64	Salicylic	60

	Potential Interferent	Highest level without interference (mg/dL)
65	Sodium	200 mM
66	Sorbitol	1000
67	Sulfamethoxazole	120
68	Sulfate	5 mM
69	Terfenadine	0.45
70	Tetracycline	10
71	Theophylline	25
72	Tolazamide	>6.25
73	Tolbutamide	64
74	Total Protein (gamma-Globulin)	12000
75	Trimopan (Trimethoprim)	12.5
76	Urea	600
77	Uric Acid	10
78	Vancomycin	25
79	Verapamil	0.45
80	Vitamin E	20
81	Warfarin	2
82	Xylitol	1000
83	Xylose	>6.25

Based on the results of their testing the sponsor listed the following limitations in the Owner's Manual and the Test Strip Insert:

- If you are taking acetaminophen containing drugs (Tylenol and other medicines containing acetaminophen, blood concentrations >6.25 mg/dL) at doses higher than recommended, these may interfere with your glucose meter and cause you to get inaccurate results with this system.
- You should know that your blood glucose results may not be reliable after a Xylose absorption test. If you have had a Xylose absorption test, or if you are unsure, ask your doctor how long you should wait until using your blood glucose meter
- If you are undergoing treatment with PAM (pralidoxime iodide, blood concentration >5 mg/dL, used in the treatment of some types of poisoning), this may cause you to get inaccurate results with this system. If you are unsure, then ask your doctor.
- If you have certain conditions that may cause your blood level of uric acid to rise (>10 mg/dL in your blood), such as gout or kidney disease, then your blood glucose results may be inaccurate with this meter.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A system accuracy study was carried out with 160 subjects at three sites to evaluate system accuracy devices in clinical and laboratory settings. Health care professionals tested subject's blood specimens via a fingertip stick using the blood glucose monitoring devices and the laboratory-based comparator method. Each blood specimen was tested with three different lots of test strips for a total of three readings per sample and tested on the analyzer. The health care professional obtained a capillary blood sample that was tested immediately using six different devices, and approximately 200µl of additional capillary blood was tested in duplicate using the laboratory analyzer at each trial site. The samples ranged in glucose concentration from 40.0 to 546 mg/dL (as measured with the laboratory-based comparator method, the YSI 2300 analyzer) for the capillary. Five samples were allowed to glycolyze in order to reach low concentrations. One sample was spiked in order to reach high concentration. Results are summarized below:

Fingertip capillary blood:

System accuracy results for glucose concentration <75 mg/dL

Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	22/26 (84.6%)	26/26 (100.0%)	26/26 (100.0%)
2	19/26 (73.1%)	26/26 (100.0%)	26/26 (100.0%)
3	16/26 (61.5%)	26/26 (100.0%)	26/26 (100.0%)

System accuracy results for glucose concentration ≥75 mg/dL

Lot	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
1	92/134 (68.7%)	128/134 (95.5%)	134/134 (100%)	134/134 (100%)
2	93/134 (69.4%)	130/134 (97.0%)	134/134 (100%)	134/134 (100%)
3	87/134 (64.9%)	128/134 (95.5%)	134/134 (100%)	134/134 (100%)

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):

Lay User Study

A lay user evaluation study was performed with 160 lay-users to determine whether glucose readings from the fingertip obtained by a lay-user provided with only the device labeling as testing instructions were comparable to results from venous whole blood measured using a laboratory-based comparator method. The labeling provided to the users was in English only. Each participant performed their own fingerstick testing using the device after reading the instructions in the proposed labeling, including the user manual and test strip manual. The samples ranged in glucose concentration from 55.9 to 449 mg/dL (as measured with the laboratory-based comparator method, the YSI 2300 analyzer). Results are summarized below:

Fingertip capillary blood:

System accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
21 /50 (42.0%)	49/50 (98.0%)	50/50 (100%)

System accuracy results for glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
57/110 (81.8%)	105/110 (95.5%)	110/110 (100%)	110/110 (100%)

Linear regression: $y = 1.0068x + 4.323$; $R^2 = 0.9904$

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The sponsor included the following Expected Values from the literature[1] for normal glucose levels in their test strip labeling:

Before eating < 100 mg/dL
Two hours after meals < 140 mg/ dL

[1] American Diabetes Association: Diabetes Care, January 2016, volume 39 (Suppl. 1 Diabetes Care): S16.

N. Instrument Name:

Smart Dongle Blood Glucose Monitoring System meter

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 _____ or No ___x____

2. Software:

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

   Yes ___x____ or No _____

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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:

   This device is intended to be used with capillary whole blood from the fingertip only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:
   No user-entered coding or calibration is required for this device.

6. Quality Control:
   The system uses FORA control solutions (three concentrations: Level 1, 2, and 3) that were previously cleared in k093724 and are provided separately from the device. Recommendations on when to test the control materials are provided in the labeling. An

acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. **Hematocrit Study:** The effect of different hematocrit levels on the performance of the Taidoc Smart Dongle Blood Glucose Monitoring System was evaluated using whole blood samples manipulated to contain hematocrit levels of 10%, 20%, 30%, 40%, 50%, 60%, and 70% and spiked with glucose (as concentrated dextrose solution; 20,000 mg/dL) to achieve concentrations that covered the claimed measurement range of 20-600 mg/dL. Each sample was then tested 6 times and the individual values were compared with those obtained from a laboratory-based comparator method, YSI 2300 analyzer. The device demonstrated adequate performance across the claimed measurement range when the hematocrit concentrations are 10% and 70%.

2. **Altitude study:** Claim: Altitude to 10,742 feet (3,275m) does not affect test results. Patient samples at 7 different glucose concentrations spanning the claimed measurement range were tested at simulated altitudes of 0, 5000, 11500, and 15000 feet elevation. Results were compared to results obtained using a laboratory-based comparator method, YSI 2300 analyzer and demonstrated that altitudes up to15,000 feet above sea level have no significant effect on blood glucose measurements from the Smart Dongle Blood Glucose Monitoring System.

3. **Temperature and humidity studies:** The sponsor performed temperature and humidity studies using blood samples with three target concentrations of glucose (~65 mg/dL, ~125 mg/dL and ~320 mg/dL) to evaluate temperatures ranging from 50ºF to 104ºF (10°C to 40°C) and relative humidity from 10% to 85%. Four meters and three lots of blood glucose test strips were evaluated and compared to results using the laboratory-based comparator method, YSI 2300 analyzer. Four temperature and humidity combinations, including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity were tested using three lots of test strips. No significant effect (relative to the reference method) was observed with any of the temperature and humidity combinations tested. The results support the claims in the labeling that the system can be used in temperatures of 50ºF to 104ºF with relative humidity of 10 to 85% (10°C to 40°C).

4. **Sample Volume Studies:** The sponsor performed sample volume studies using venous blood altered to three target glucose concentrations (30-50, 96-144, and 280-420 mg/dL). At each target concentration, samples of different volumes (0.8, 0.9, 1.0, 1.1, 1.2, and 1.3 µl) were measured with the device and compared to results from a laboratory-based comparator method, YSI 2300 analyzer. Three lots of test strips and 5 meters were evaluated. The results support the claimed minimal sample volume of 1.0 µl.

5. **Infection Control Studies:** The Smart Dongle Glucose Monitoring System is intended for single-patient use. Microkill Plus (EPA Reg.No.59894-10-37549) were validated by an outside testing laboratory to demonstrate complete inactivation of live virus. The

sponsor also demonstrated that there was no change in performance of the Smart Dongle glucose meter after 10950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate ten cycles of cleaning and disinfection per day over three years. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. **Software:** Software documentation was reviewed and demonstrated that the device was developed under appropriate software lifecycle processes.

7. **Electromagnetic Compatibility (EMC) testing:** The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the device systems were found to be compliant.

8. Customer service is available at 1-888-307-8188 (7:00 am - 6:00 pm PST, Mon. - Fri.). The sponsor indicates that users who need assistance outside of these hours should contact their healthcare professional.

9. **Readability**: The readability of the Smart Dongle BGMS, and Smart Dongle Blood Glucose Test Strip user manuals were evaluated. The Smart Dongle BGMS user manual and Smart Dongle Test strip manual scored 8.0 and 7.9 respectively on the Flesch-Kincaid scale.

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.