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

A. 510(k) Number:

K101631

B. Purpose for Submission:

New Device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose dehydrogenase (FAD-GDH)

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

CHOICE DM® Complete by FORA GD20 Blood Glucose Monitoring System,
URIGHT TD-4252 Blood Glucose Monitoring System, and
FORA Control Solution.

G. Regulatory Information:

Device	Product Code	Classification	Regulation Section	Panel
CHOICE DM® Complete by FORA GD20 Blood Glucose Monitoring System, model FORA GD20	LFR	Class II	21 CFR § 862.1345, Glucose dehydrogenase, glucose test system	75-Chemistry
URIGHT TD-4252 Blood Glucose Monitoring System, model TD-4252	LFR, NBW (over the counter)	Class II	21 CFR § 862.1345, Glucose dehydrogenase, glucose test system, over the counter	75-Chemistry
FORA Control Solution	JJX	Class I, reserved	21 CFR § 862.1660, Quality Control material	75-Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   Device Name: CHOICE DM® COMPLETE by FORA GD20 Blood Glucose Monitoring System

   The CHOICE DM® COMPLETE by FORA GD20 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in venous whole blood or fresh capillary whole blood (from the finger, palm, forearm and upper arm). It is intended for multiple patient uses in professional healthcare settings as an aid to monitoring the effectiveness of diabetes control. It should not be used for the diagnosis of or screening for diabetes, or testing on neonates.

   The CHOICE DM® COMPLETE by FORA GD20 test strips are for use with the CHOICE DM® COMPLETE by FORA GD20 meter to quantitatively measure glucose (sugar) in venous whole blood or fresh capillary whole blood samples drawn from fingertips, palm, forearm and upper arm.

   This system is only used with single-use, auto-disabling lancing device.

   Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

   The FORA control solutions are for use with the CHOICE DM® COMPLETE by FORA GD20 meter and test strips to check that the meter and test strips are working together properly and that the test is performing correctly..

   Device Name: U-RIGHT TD-4252 Blood Glucose Monitoring System

   The U-RIGHT TD-4252 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood (from the finger, palm, forearm and upper arm). It is intended for use by people with diabetes at home as an aid to monitoring the effectiveness of diabetes control. It should not be used for the diagnosis of or screening for diabetes, or testing on neonates.

   This system is intended to be used by a single person and should not be shared.

   The U-RIGHT TD-4252 test strips are for use with the U-RIGHT TD-4252 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, forearm and upper arm.

   Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The FORA control solutions are for use with the U-RIGHT TD-4252 meter and test strips to check that the meter and test strips are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):

Not for neonatal use, not for screening or diagnosis of diabetes mellitus.

Not for use on critically ill patients, patients in shock, severely hypotensive individuals, dehydrated patients or individuals experiencing hyperglycaemic-hyperosmolar state, with or without ketosis.

Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.

AST testing should only be done during steady-state times (when glucose is not changing rapidly).

Multiple user devices (FORA GD20) must be disinfected between users following labeling recommendations.

Multiple patient use settings are to use disposable, single use lancing devices with the meters.

4. Special instrument requirements:

CHOICE DM® COMPLETE by FORA GD20 glucose meter

URIGHT TD-4252 glucose meter

I. Device Description:

The systems consist of three main components: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results.

The CHOICE DM® COMPLETE by FORA GD20 Blood Glucose Monitoring System consists of FORA GD20 meter, FORA GD20 test strips (sold separately), FORA control solutions (sold separately), and auto-disabling single use lancing devices (sold separately). The FORA GD20 meter is a “no code” meter and can be operated from 50°F to 104°F (10°C to 40°C), below 85% RH (non-condensing). The device can be used to measure whole blood glucose in venous or fresh capillary samples from the fingertips, palm, forearm and upper arm. The FORA GD20 meter has 4 alarm settings, easy-slide strip ejector and a 448 test memory with date and time. The chemical components in FORA GD20 test strip sensor are 5% FAD-GDH (*E. coli*), 30% electron shuttle, 4% enzyme protector and 61% non-reactive ingredients. The user manual describes disinfection instructions for using the device in multiple patient use settings.

U-RIGHT TD-4252 Test strips for U-RIGHT TD-4252 Blood Glucose Monitoring System consists of U-RIGHT TD-4252 meter, U-RIGHT TD-4252 Test strips (sold separately), FORA control solutions (sold separately), and the adjustable height lancing device (sold separately). The U-RIGHT TD-4252 meter is a "no code" meter and can be operated from 50°F to 104°F (10°C to 40°C), below 85% RH (non-condensing). The device can be used to measure whole blood glucose in fresh capillary samples from the fingertips, palm, forearm and upper arm. The U-RIGHT TD-4252 meter has 4 alarm settings, easy-slide strip ejector and a 448 test memory with date and time. The chemical components in U-RIGHT TD-4252 test strip sensor are 5% FAD-GDH (*E. coli*), 30% electron shuttle, 4% enzyme protector and 61% non-reactive ingredients.

The FORA control solutions are red aqueous solutions which contains of 0.03% to 0.3% D-glucose as an active ingredient and >99.7% of inert ingredients. The FORA control solutions are available at three levels. The control solutions give accurate results when tested at 68°F to 77°F (20°C to 25°C).

J. Substantial Equivalence Information:

1. Predicate device name(s):

   TaiDoc Professional I Glucose Test Strips with Clever Chek TD-4222

2. Predicate K number(s):

   k082169

3. Comparison with predicate:

   The CHOICE DM® COMPLETE by FORA GD20 Blood Glucose Monitoring System/ U-RIGHT TD-4252 Blood Glucose Monitoring System have the following similarities and differences to the predicate device:

Items	Predicate Device	Candidate Devices	
Brand Name	TaiDoc Professional I Glucose Test Strips with Clever Chek TD-4222 (k082169)	CHOICE DM® Complete by FORA GD20 Blood Glucose Monitoring System	U-RIGHT TD-4252 Blood Glucose Monitoring System
Model No.	Clever Chek TD-4222	FORA GD20	TD-4252
Similarities			
Indications for Use	Intended for use in the quantitative measurement of glucose with fresh capillary whole blood from	Same	Same

	finger, as an aid in monitoring the effectiveness of diabetes control program		
Operating Principle	Electrochemical Biosensor Technology	Same	Same
Detection Method	Amperometry	Same	Same
Enzyme	FAD-GDH	Same	Same
Operation Condition	50°F to 104°F (10°C to 40°C), below 85% R.H.	Same	Same
Sample Volume (µL)	0.7 µL	Same	Same
Reaction Time (sec)	7 seconds	Same	Same
Measurement Range	20 to 600 mg/dL	Same	Same
Test Strip Shelf Life	18 months	Same	Same
Test Strip Storage / Transportation condition	35.6°F to 89.6°F (2°C to 32°C), below 85% R.H.	Same	Same
Differences			
Calibration	N/A	No coding required	No coding required
Sample type	Capillary and venous whole blood	Same as the predicate	Capillary whole blood
AST	Palm, forearm, upper arm, calf and thigh	Palm, forearm and upper arm	Palm, forearm and upper arm,

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

ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

ISO 14971:2007, Medical devices - Application of risk management to medical devices

CLSI EP-6P Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach

CLSI EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition

CEN 13640 Stability Testing of In Vitro Diagnostic Reagents

L. Test Principle:

The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose dehydrogenase. The CHOICE DM® COMPLETE by FORA GD20 Blood Glucose Monitoring System and the U-RIGHT TD-4252 Blood Glucose Monitoring System employs flavin adenine dinucleotide-glucose dehydrogenase (FAD-GDH) enzyme chemistry as the standard dry reagent assay for glucose in whole blood. This enzyme assay, with a redox chemical "mediator" reaction, is used to generate an electrical current proportional to the glucose concentration in the blood sample. The system is designed as an amperometric measurement device using current generated from the redox reaction as the measurable response.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

The CHOICE DM® COMPLETE by FORA GD20 Blood Glucose Monitoring System

The repeatability study was performed by one operator using heparinized anti-coagulated whole blood (hematocrit ranged between 38%-54%) at five different glucose concentrations. The final glucose concentrations for the blood samples were confirmed by YSI. Each sample was tested on ten meters using three lots of test strips (three meters with each of the two test strip lots and four meters with one test strip lot). Ten measurements were obtained per meter and test strip lot, and glucose concentration (N=100 per concentration level). The result is summarized below:

Repeatability

Range (mg/dL)	N	FORA GD20 BGMS		
		Mean (mg/dL)	SD	CV%
30-50 mg/dL	100	39.5	2.1	5.3
51-110 mg/dL	100	81.2	2.98	3.7
111-150 mg/dL	100	132.9	5.03	3.79
151-250 mg/dL	100	210.8	6.7	3.18
251-400 mg/dL	100	363.0	9.15	2.52

Intermediate precision studies were performed by one operator using three levels of control solutions. Each sample was tested on ten meters using three lots of test strips (three meters with each of the two test strip lots and four meters with one test strip lot) for ten days (N=100 per concentration level).

Intermediate Precision

Control solution	N	Mean (mg/dL)	SD	CV%
30-50 mg/dL	100	40.7	1.93	4.7
96-144 mg/dL	100	137.3	4.53	3.3
267-401 mg/dL	100	327.8	11.78	3.59

The U-RIGHT TD-4252 Blood Glucose Monitoring System

The repeatability study was performed by one operator using heparinized anti-coagulated whole blood (hematocrit approximately 45%) at seven different glucose concentrations. The final glucose concentrations for the blood samples were confirmed by YSI. Each sample was tested on ten meters using three lots of test strips (three meters with each of the two test strip lots and four meters with one test strip lot). Ten measurements were obtained per meter and test strip lot, and glucose concentration (N=100 per concentration level). The result is summarized below:

Repeatability

Range (mg/dL)	N	U-RIGHT TD-4252 BGMS		
		Mean (mg/dL)	SD	CV%
15-25 mg/dL	100	21.69	1.37	6.3
30-50 mg/dL	100	42.23	3.21	7.6
51-110 mg/dL	100	87.32	2.42	2.8
111-150 mg/dL	100	125.55	3.73	3.0
151-250 mg/dL	100	206.13	5.47	2.7
251-400 mg/dL	100	300.87	7.62	2.5
550-650 mg/dL	100	572.95	14.54	2.5

Intermediate precision studies were performed by one operator using five levels of control solutions. Each sample was tested on ten meters using three lots of test strips (three meters with each of the two test strip lots and four meters with one test strip lot) for 10 days (N=100 per concentration level).

Intermediate Precision

Control solution	N	Mean (mg/dL)	SD	CV%
15-25 mg/dL	100	21.34	1.19	5.6
30-50 mg/dL	100	39.78	1.41	3.5
96-144 mg/dL	100	120.82	2.25	1.87
280-420 mg/dL	100	334.42	5.71	1.71
550-650 mg/dL	100	594.41	5.01	0.84

b. *Linearity/assay reportable range:*

Linearity study was designed based on CLSI EP6-A guideline.

The CHOICE DM® COMPLETE by FORA GD20 Blood Glucose Monitoring System

Eleven venous blood samples spiked with dextrose that covered the range from 20-600 mg/dL (hematocrit 45%). Glucose concentrations (21.1, 45.2, 73.1, 109, 185, 265, 356 and 728 mg/dL) were confirmed by the YSI. One operator performed the study using five meters and three test strip lots in singlicate (N=55 per test strip lot). The results are summarized below:

Strip Lot	Slope	Intercept	R^2
Lot 1	1.0022	-3.2999	0.9952
Lot 2	1.011	-3.2894	0.9967
Lot 3	1.0001	-3.6644	0.9958
Three lots combined	1.0044	-3.4179	0.998

The measurement range of the FORA GD20 Blood Glucose Monitoring System is 20 to 600 mg/dL.

The U-RIGHT TD-4252 Blood Glucose Monitoring System

Eleven venous blood samples spiked with dextrose that covered the range from 20-600 mg/dL (hematocrit 45%). Glucose concentrations (21.1, 45.2, 73.1, 109, 185, 265, 356 and 728 mg/dL) were confirmed by the YSI. One operator performed the study using five meters and three test strip lots in singlicate (N=55 per test strip lot). The results are summarized below:

Strip Lot	Slope	Intercept	R^2
Lot 1	0.9977	-2.5733	0.9979
Lot 2	0.9892	-0.0531	0.9965
Lot 3	0.9913	-2.399	0.996
Three lots combined	0.9927	-1.6751	0.9983

The measurement range of the U-RIGHT TD-4252 Blood Glucose Monitoring System is 20 to 600 mg/dL.

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

<u>FORA control solutions</u>:

The FORA control solutions are traceable to the NIST SRM 917A reference material and YSI-2300. Value assignment was performed with 25 meters, 25 vials of test strips from the same lot and 3 levels of control solutions. The mean, standard deviation and CV are calculated for each new lot of control material. The control range for each strip lot must be within mean ± 20% and CV ≤ 5%. The target means and acceptable ranges for control solutions 1, 2

and 3 are 52.35 mg/dL (41.88 to 62.82 mg/dL), 154.79 mg/dL (123.83 to 185.75 mg/dL), and 314.63 mg/dL (251.7 to 377.56 mg/dL), respectively.

Open vial control stability was tested at three control levels on three lots. Based on these studies, open vial stability is 90 days when stored at 35.6°F and 86°F (2°C and 30°C) below 85% R.H. Unopened vial control stability was tested in real time at three control levels on three lots. Unopened control solutions were tested under identical conditions as the opened control solutions. The Unopened control solutions have a 24 month shelf life when stored at 35.6°F and 86°F (2°C and 30°C) below 85% R.H. Stability studies protocol and acceptance criteria for open and unopened vials were provided and found to be adequate.

FORA GD20 and U-RIGHT TD-4252 Glucose Test Strips:

Real time stability was performed separately for FORA GD20 and U-RIGHT TD-4252 glucose test strips to assess the shelf-life and open-vial stability of the test strips. Stability studies protocol and acceptance criteria were provided and found to be adequate. The sponsor claimed that the unopened test strips have a 18 month shelf-life and are stable for 3 months after opening when stored at 35.6°F - 86°F (2°C - 30°C) below 10 - 85% R.H.

This information is provided in the labeling of the test strips and control materials.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on the linearity/assay reportable range study above (section M.1.b).

e. *Analytical specificity:*

Interference study was designed according to CLSI EP7-A2 guideline for the CHOICE DM® COMPLETE by FORA GD20 Blood Glucose Monitoring System and the U-RIGHT TD-4252 Blood Glucose Monitoring System. Identical results were obtained for both the systems.

75 common potential endogenous and exogenous interfering substances were evaluated by spiking venous blood with two levels of glucose concentrations (85 mg/dL and 130 mg/dL). The glucose samples were spiked with the potentially interfering compounds and tested on four meters. Several concentrations of the interfering substances were tested as shown in the table below. Non interfering substances were tested at toxic level concentrations or 10 times the highest therapeutic concentrations as recommended in CLSI EP7-A2 guidance. The sugar and alcohol substances with unknown blood concentration were tested at 1000 mg/dL. If the blood concentration of the substance is not known, the concentration tested was three times the therapeutic dose distributed in 5L of blood. Bias was calculated as the mean

percent difference in glucose reading between the test and control concentration groups. Significant interference is defined by the sponsor as a bias ≥ 10 % from the control group as measured on YSI.

The sponsor claims no significant interference (< 10% difference) for the substances and concentrations shown in the table below:

Interferent*	Concentration tested (mg/dL)
Gentisic Acid	2
Aspirin	60
Ibuprophen	55
Acetylsalicylic acid	50
Tetracycline	4
Tolbutamide	64
Galactose	1000
Maltose	1000
Mannitol	1000
Sorbitol	1000
Lactose	1000
Fructose	1000
Hemoglobin	500
Cholesterol	500
Creatinine	5
Triglycerides	2000
Furosemide	2
Ascorbic acid	4
Bilirubin (Unconjugated)	20

*All the substances tested in interference study are not shown.

Interference was observed with the substances in excess of limiting concentrations listed below:

Interferent	Limiting Concentration (mg/dL)	Concentrations tested (mg/dL)
Acetaminophen	6.25	5,10, 15, 20
Dopamine	1.25	0.625, 1.25, 2.5, 5, 10
Levo-Dopa	0.7	0.35, 0.7, 1.4, 2.8
Mannose	125	31.25, 62.5, 125, 250, 500, 1000
Methyl-Dopa	1.25	0.31, 0.63, 1.25, 2.5
Tolazamide	12.5	3.13, 6.25, 12.5, 25
Xylose	3.125	3.125, 6.25, 12.5, 25
Uric Acid	10.0	5, 10, 15, 20

Hematocrit Study:

The effect of different hematocrit levels on the accuracy of the devices was

evaluated on the FORA GD20 Blood Glucose Monitoring System and the U-RIGHT TD-4252 Blood Glucose Monitoring System using six meters of each device, and one test strip lot. Blood samples at nine hematocrit levels from 20% to 60% (20, 25, 30, 35, 40, 45, 50, 55 and 60%) were evaluated in seven concentrations of glucose of approximately 60, 100, 160, 265, 350, 480 and 600 mg/dL. Glucose concentrations were compared to YSI. No significant interference from hematocrit was defined as bias within ± 15%. Results that demonstrated that hematocrit levels between 20%-60% do not significantly interfere with glucose measurements.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The CHOICE DM® COMPLETE by FORA GD20 Blood Glucose Monitoring System

The method comparison and AST studies were conducted at three sites by three technicians at each site, using three test strip lots (one strip lot per site) and two meters. Healthcare professionals performed two fingertip capillary blood glucose measurements on two glucose meters from a total of 150 subjects followed by testing in duplicate by YSI within 5 minutes. Similarly healthcare professionals performed two measurements at each of the claimed AST sites (palm, forearm and upper arm) each followed by testing in duplicate by YSI. The glucose concentration of the samples spanned the measuring range following the ISO 15197 guidelines for distribution of samples (at each site). Distribution of glucose concentrations across the measuring range was: 9 samples between < 50 mg/dL, 20 samples between 50 - 80 mg/dL, 32 samples between 81 - 120 mg/dL, 43 samples between 121 - 200 mg/dL, and 23 samples between 201 - 300 mg/dL. Of the 150 samples, eight samples (for concentrations below 50 mg/dL) were glycolyzed and nine samples (for concentrations above 400 mg/dL) were spiked. The meters were cleaned between each patient use following the protocol described in the labeling with the recommended disinfectant wipes. The studies met ISO 15197 accuracy criteria, e.g., 95% of glucose results < 75 mg/dL were within ± 15 mg/dL, and for samples ≥ 75 mg/dL, 95% of results were within ± 20% of the reference method. Results are summarized below:

Healthcare Professional Fingertip vs. YSI

Meter	Slope	Y-intercept	R2
GD20-1	1.005	-1.2542	0.989
GD20-2	0.9849	0.9424	0.9826

Healthcare Professional Fingertip vs. YSI < 75 mg/dL

Meter	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
GD20-1	21/26 (81%)	25/26 (96%)	26/26 (100%)
GD20-2	19/26 (73%)	25/26 (96%)	26/26 (100%)

Healthcare Professional Fingertip vs. YSI ≥ 75 mg/dL

Meter	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
GD20-1	68/124 (55%)	113/124 (91%)	122/124 (98%)	124/124 (100%)
GD20-2	54/124 (44%)	113/124 (85%)	121/124 (98%)	124/124 (100%)

Healthcare Professional AST vs. YSI

Meters 1 & 2	**Slope**	**Intercept**	**R_2**
Palm 1	1.0019	- 0.0367	0.9868
Palm 2	1.0085	- 1.6927	0.9855
Forearm 1	1.0063	- 0.3313	0.9885
Forearm 2	1.0058	1.2364	0.9858
Upper arm 1	1.0118	- 1.6942	0.9879
Upper arm 2	1.0172	-2.2486	0.986

Healthcare Professional AST vs. YSI < 75 mg/dL

Meters 1 & 2	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Palm 1	22/26 (85%)	25/26 (96%)	26/26 (100%)
Palm 2	19/26 (73%)	25/26 (96%)	26/26 (100%)
Forearm 1	23/26 (85%)	26/26 (100%)	26/26 (100%)
Forearm 2	20/26 (85%)	25/26 (96%)	26/26 (100%)
Upper arm 1	22/26 (85%)	25/26 (96%)	26/26 (100%)
Upper arm 2	22/26 (85%)	26/26 (100%)	26/26 (100%)

Healthcare Professional AST vs YSI ≥ 75 mg/dL

Meters 1 & 2	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Palm 1	62/124 (50%)	98/124 (79%)	123/124 (99%)	124/124 (100%)
Palm 2	51/124 (41%)	101/124 (81%)	121/124 (98%)	124/124 (100%)
Forearm 1	64/124 (52%)	100/124 (81%)	123/124 (99%)	124/124 (100%)
Forearm 2	48/124 (39%)	93/124 (75%)	119/124 (96%)	124/124 (100%)
Upper arm 1	60/124 (44%)	106/124 (85%)	119/124 (96%)	123/124 (99%)
Upper arm 2	52/124 (42%)	95/124 (77%)	118/124 (95%)	123/124 (99%)

The U-RIGHT TD-4252 Blood Glucose Monitoring System

The method comparison/accuracy study using this meter, as well as the lay user studies were conducted at three sites by 133 lay users and three

technicians/healthcare professionals at each site, using three test strip lots (one strip lot per site). Lay users were provided with labeling in English. Lay users performed finger stick to test their blood with a meter followed by the healthcare professional performing two fingertip capillary blood glucose measurements on two glucose meters from a total of 133 subjects followed by testing in duplicate by YSI within 5 minutes. Similarly lay users performed testing of each of the AST sites using a meter followed by the healthcare professional performing two measurements using two glucose meters at each of the claimed AST sites (palm, forearm and upper arm), each followed by testing in duplicate by YSI. The glucose concentration of the samples spanned between 50 to 400 mg/dL at each site. The meters were cleaned between each patient use following the protocol described in the labeling with the recommended disinfectant wipes. The studies met ISO 15197 accuracy criteria, e.g., 95% of glucose results < 75 mg/dL were within ± 15 mg/dL, and for samples ≥ 75 mg/dL, 95% of results were within ± 20% of the reference method. Results are summarized below:

Lay User Fingertip vs. YSI

Meter	Slope	Y-intercept	R2
TD-4252	0.9932	2.3622	0.9687

Healthcare Professional Fingertip vs. YSI

Meter	Slope	Y-intercept	R2
TD-4252-1	0.9932	2.3622	0.9687
TD-4252-2	0.9805	5.0718	0.9719

Lay User Fingerstip vs YSI < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7/18 (39%)	17/18 (94%)	18/18 (100%)

Lay User Fingertip vs YSI ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
43/115 (37%)	79/115 (69%)	112/115 (97%)	115/115 (100%)

Healthcare Professional Fingertip vs. YSI < 75 mg/dL

Meter	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
GD20-1	12/18 (67%)	18/18(100%)	18/18 (100%)
GD20-2	14/18 (78%)	18/18 (100%)	18/18 (100%)

Healthcare Professional Fingertip vs. YSI ≥ 75 mg/dL

Meter	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
GD20-1	50/115 (43%)	93/115 (81%)	111/115 (97%)	115/115 (100%)
GD20-2	39/115 (34%)	85/115 (74%)	109/115 (95%)	115/115 (100%)

Lay User AST vs. YSI

Meter	Slope	Intercept	R_2
Palm	0.9754	5.2169	0.9633
Forearm	0.9493	9.0974	0.9679
Upper arm	0.9274	11.201	0.9615

Healthcare Professional AST vs. YSI

Meters 1 & 2	Slope	Intercept	R_2
Palm 1	1.0191	1.7016	0.9825
Palm 2	1.0176	1.2775	0.9778
Forearm 1	0.9992	2.4729	0.9815
Forearm 2	1.0112	0.2217	0.9724
Upper arm 1	1.0283	- 0.7665	0.9779
Upper arm 2	1.0363	-3.2232	0.9736

Lay User AST vs. YSI < 75 mg/dL

AST	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Palm	7/19 (37%)	18/19 (95%)	19/19 (100%)
Forearm	8/17 (47%)	17/17 (100%)	17/17 (100%)
Upper arm	9/18 (50%)	17/18 (94%)	18/18 (100%)

Lay User AST vs YSI ≥ 75 mg/dL

AST	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Palm	24/114 (21%)	65/114 (57%)	109/114 (96%)	114/114 (100%)
Forearm	34/116 (29%)	77/116 (66%)	111/116 (96%)	116/116 (100%)
Upper arm	29/115 (25%)	78/115 (68%)	110/115 (96%)	115/115 (100%)

Healthcare Professional AST vs. YSI < 75 mg/dL

Meters 1 & 2	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Palm 1	12/18 (67%)	18/18 (100%)	18/18 (100%)
Palm 2	10/18 (56%)	17/18 (94%)	18/18 (100%)
Forearm 1	8/18 (44%)	18/18 (100%)	18/18 (100%)
Forearm 2	13/18 (72%)	18/18 (100%)	18/18 (100%)
Upper arm 1	14/18 (78%)	18/18 (100%)	18/18 (100%)
Upper arm 2	13/18 (72%)	17/18 (94%)	18/18 (100%)

Healthcare Professional AST vs YSI ≥ 75 mg/dL

Meters 1 & 2	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Palm 1	61/115 (53%)	95/115 (83%)	112/115 (97%)	115/115 (100%)
Palm 2	44/115 (38%)	89/115 (77%)	115/115 (100%)	115/115 (100%)
Forearm 1	59/115 (51%)	99/115 (86%)	113/115 (98%)	115/115 (100%)
Forearm 2	38/115 (33%)	83/115 (72%)	114/115 (99%)	115/115 (100%)
Upper arm 1	54/115 (47%)	80/115 (70%)	110/115 (96%)	115/115 (100%)
Upper arm 2	39/115 (34%)	79/115 (69%)	107/115 (93%)	115/115 (100%)

b. *Matrix comparison:*

FORA GD20 BGMS

Anticoagulant comparison studies for FORA GD20 BGMS were performed with venous whole blood collected in K3-EDTA and sodium heparin from a total of 150 subjects. The study was performed at three clinical sites by three technicians at each site, using three test strip lots (one strip lot per site) and two meters. The venous whole blood samples were collected in commercially marketed drawing tubes containing anticoagulant K3-EDTA (at site 2) and sodium heparin (at site 1 and 3). The glucose concentration of the samples spanned the measuring range following the ISO 15197 guidelines for distribution of samples (at each site). Of the 150 samples, eight samples (for concentrations below 50 mg/dL) were glycolyzed and nine samples (for concentrations above 400 mg/dL) were spiked. The accuracy was evaluated by comparing the FORA GD20 meter measurements to YSI at three sites.

Site / Meter	Anticoagulant	Slope	Y-intercept	R2
1 / GD20-1	Sodium Heparin	0.9885	1.2176	0.9875
1 / GD20-2		1.0026	1.2236	0.9862
2 / GD20-1	K3-EDTA	1.0227	2.6489	0.9873
2 / GD20-2		1.0427	-0.0523	0.9845
3 / GD20-1	Sodium Heparin	1.0124	3.1539	0.9784
3 / GD20-2		0.9932	4.8527	0.9627

Test Strip Lot 1 / Sodium Heparin vs YSI < 75 mg/dL

Meter	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
GD20-1	7/10 (70%)	10/10 (100%)	10/10 (100%)
GD20-2	8/10 (80%)	9/10 (90%)	10/10 (100%)

Test Strip Lot 1 / Sodium Heparin vs YSI ≥ 75 mg/dL

Meter	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
GD20-1	20/40 (50%)	34/40 (88%)	39/40(98%)	40/40 (100%)
GD20-2	10/40 (48%)	33/40 (83%)	38/40 (95%)	40/40 (100%)

Test Strip Lot 2 / K3-EDTA vs YSI < 75 mg/dL

Meter	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
GD20-1	7/10 (70%)	10/10 (100%)	10/10 (100%)
GD20-2	9/10 (90%)	10/10 (100%)	10/10 (100%)

Test Strip Lot 2 / K3-EDTA vs YSI ≥ 75 mg/dL

Meter	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
GD20-1	17/40 (43%)	28/40 (70%)	37/40(93%)	40/40 (100%)
GD20-2	20/40 (50%)	28/40 (70%)	36/40 (90%)	40/40 (100%)

Test Strip Lot 3 / Sodium Heparin vs YSI < 75 mg/dL

Meter	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
GD20-1	4/6 (67%)	6/6 (100%)	6/6 (100%)
GD20-2	5/6 (83%)	6/6 (100%)	6/6 (100%)

Test Strip Lot 3 / Sodium Heparin vs YSI ≥ 75 mg/dL

Meter	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
GD20-1	17/44 (39%)	32/40 (73%)	42/44(98%)	44/44 (100%)
GD20-2	16/44 (36%)	28/40 (64%)	37/44 (95%)	43/44 (98%)

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):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected blood glucose values for normal people without diabetes is cited from the literature[1] and presented in the labeling as follows:

Fasting and before meal: Less than 100 mg/dL (5.6 mmol/L)
2 hours after meal: Less than 140 mg/dL (7.8 mmol/L)

[1]American Diabetes Association (2010), Clinical Practice Recommendations, Diabetes Care 33 (Supplement 1): S1-100.

N. Instrument Name:

FORA GD20 Blood Glucose Meter
U-URIGHT TD-4252 Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 0.7 uL.

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 _____

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, palm, forearm and upper arm only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The FORA GD20 and the U-RIGHT TD-4252 meters are no code devices. Reaction intensities of new test strip lots must meet the manufacturer's no code criteria for use with these meters. Validation of new strip lots is confirmed by comparison to the YSI across the measuring range of the device.

6. Quality Control:

   Glucose control solutions at three different concentrations can be run with the FORA GD20 and the U-RIGHT TD-4252 devices. These meters have a 'C button' to mark the test with control solutions to prevent control results from being stored in the internal memory as patient results. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. 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. A usability study was performed to assess the readability of the labeling by recruiting 133 lay users (aged 18-70 yrs old) who were provided with the test kit containing labeling in English for the US market. Participants varied in age, education, country of origin, and were about evenly divided between men and women. These lay users also completed a questionnaire to indicate whether the device is easy to use and the Instructions for use were written in a way that makes it easy to use. The majority of the users responded that the device is very easy to use.

2. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User Guide, test strip package insert and control solution package insert) were written at grade levels ranging from 7.0^{th} to 8.0^{th} grade.

3. Customer service is available 24/7, 365 days a year. Toll free phone numbers are 1-888-307-8188 and 1-866-469-2632 for customer support.

4. Insufficient sample studies were performed (separately for FORA GD20 and U-RIGHT TD-4252 BGMS) at 0.5, 0.6, 0.7, 0.8, 1.0, 1.5 and 2 µL volumes around the recommended volume (0.7 µL) using three test strip lots. Each sample was tested five times per strip lot. Three glucose concentration levels of venous whole blood and control solutions were tested (level 1 30-50 mg/dL, level 2 96-144 mg/dL and level 3 280-420 mg/dL) as determined by the YSI. Appropriate sample volume was determined if the meter results compared to YSI results were within 10% bias for blood samples and less than 5% CV for control solutions. A blood volume ≥ 0.6 µL met the criteria.

5. Temperature and humidity operating conditions were evaluated for temperatures ranging from 50°F to 104°F (10°C to 40°C) and relative humidity from 10% to 85% R.H. The sponsor tested combination of lowest and highest temperature with lowest and highest humidity. The study protocol and acceptance criteria were provided and found to be acceptable. The results supported the Sponsor's claimed operating temperature from 50°F to 104°F (10°C to 40°C) and relative humidity from 10% to 85%.

6. The effect of altitude on the accuracy of the device was evaluated on the FORA GD20 Blood Glucose Monitoring System and the U-RIGHT TD-4252 Blood Glucose Monitoring System with four meters and one test strip lot. Blood samples at seven concentrations of glucose of approximately 70, 115, 190, 275, 390, 450 and 630 mg/dL were tested at three altitude levels (5000, 11500 and 15000 feet) and at sea level (0 feet). Testing was performed in an altitude simulation glove box system. Each sample was also tested by YSI-2300. No significant interference from altitude was defined by the sponsor as bias within ±10%. The data demonstrates that elevation of 11, 500 and 15, 000 feet does not affect the accuracy of the two devices. Based on the data, the sponsor claims that the FORA GD20 Blood Glucose Monitoring System and the U-RIGHT TD-4252 Blood Glucose Monitoring System can be used at altitude up to 10, 742 feet.

7. The FORA GD20 BGMS is intended for multiple patient use by healthcare professionals and U-RIGHT TD-4252 is intended for home use by single person. Disinfection studies were performed on the FORA GD20 meter and TD-4252 meter by an outside commercial testing service to determine the robustness of the meter and lancing device to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV). Micro-Kill+™ (Micro-Kill Plus) by

Medline disposable wipes (EPA Reg. No.59894-10-37549) was validated, demonstrating complete inactivation of live virus for use with the FORA GD20 and TD-4252 meters. The sponsor demonstrated that there was no change in performance or in the external materials of the FORA GD20 meter after 10,000 cleaning and disinfection cycles to simulate an estimated 9 cleaning and disinfection cycles per day over 3 years of healthcare professional use. The sponsor also demonstrated that there was no change in performance or in the external materials of the U-RIGHT TD-4252 meter after 5000 cleaning and disinfection cycles to simulate an estimated 4 cleaning and disinfection cycles per day over 3 year use. Labeling has been reviewed for adequate instructions on the validated cleaning and disinfection procedures.

8. EMC testing was evaluated and certified by SGS Taiwan Ltd. and a letter of attestation was issued to TaiDoc Technology Corp. on August 25, 2011.

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.