

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

A. 510(k) Number:

k101509

B. Purpose for Submission:

New devices

C. Measurand:

Capillary and venous whole blood glucose

D. Type of Test:

Whole blood glucose concentration through a quantitative amperometric assay (GDH-FAD)

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

U-RIGHT TD-4279A Blood Glucose Monitoring System

U-RIGHT TD-4279B Blood Glucose Monitoring System

U-RIGHT TD-4279A MULTI Blood Glucose Monitoring System

U-RIGHT TD-4279B MULTI Blood Glucose Monitoring System

FORA GD40a/TD-4272a Blood Glucose Monitoring System

FORA GD40b/TD-4272b Blood Glucose Monitoring System

FORA Wisdom GD40a/TD-4272a Blood Glucose Monitoring System

FORA Wisdom GD40b/TD-4272b 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, Blood Glucose Test System, Over-the-Counter

LFR, Glucose Dehydrogenase

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indication for use below.

2. Indication(s) for use:

For single patient use

U-RIGHT TD-4279A Blood Glucose Monitoring System

The U-Right TD-4279A Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The U-Right TD-4279A 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 neonatal use.

The U-Right TD-4279 A Test Strips are for use with the U-Right TD-4279A Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

U-RIGHT TD-4279B Blood Glucose Monitoring System

The U-Right TD-4279B Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The U-Right TD-4279B 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 neonatal use.

The U-Right TD-4279B Test Strips are for use with the U-Right TD-4279B Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

FORA GD40a Blood Glucose Monitoring System

The FORA GD40a / TD-4272A Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The FORA GD40a / TD-4272A 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 neonatal use.

The FORA GD40a / TD-4272A Test Strips are for use with the FORA GD40a / TD-4272A Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

FORA GD40b Blood Glucose Monitoring System

The FORA GD40b / TD-4272B Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. This blood glucose monitoring system is intended to be used by a single person and should not be shared.

The FORA GD40b / TD-4272B 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 neonatal use.

The FORA GD40b / TD-4272B Test Strips are for use with the FORA GD40b / TD-4272B Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

For multiple patient use**U-RIGHT TD-4279A MULTI Blood Glucose Monitoring System**

The U-Right TD-4279A MULTI 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 fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The U-Right TD-4279A MULTI Test Strips are for use with the U-Right TD-4279A MULTI Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

U-RIGHT TD-4279B MULTI Blood Glucose Monitoring System

The U-Right TD-4279B MULTI 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 fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The U-Right TD-4279B MULTI Test Strips are for use with the U-Right TD-4279B MULTI Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

FORA Wisdom GD40a Blood Glucose Monitoring System

The FORA Wisdom GD40a / TD-4272A 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 fingertip. Testing is done outside

the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The FORA Wisdom GD40a / TD-4272A Test Strips are for use with the FORA Wisdom GD40a / TD-4272A Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

FORA Wisdom GD40b Blood Glucose Monitoring System

The FORA Wisdom GD40b / TD-4272B 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 fingertip. Testing is done outside the body (In Vitro diagnostic use). This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use lancing devices. This system is not to be used on neonates, nor for the diagnosis of, or screening for diabetes mellitus.

The FORA Wisdom GD40b / TD-4272B Test Strips are for use with the FORA Wisdom GD40b / TD-4272B Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary and venous whole blood samples drawn from the fingertips.

3. Special conditions for use statement(s):

- Not intended for diagnosis or screening of diabetes mellitus
- Over the Counter Use - U-RIGHT TD-4279A Blood Glucose Monitoring System, U-RIGHT TD-4279B Blood Glucose Monitoring System, FORA GD40a / TD-4272A Blood Glucose Monitoring System, FORA GD40b / TD-4272B Blood Glucose Monitoring System
- Over the Counter and Prescription Use - U-RIGHT TD-4279A MULTI Blood Glucose Monitoring System, U-RIGHT TD-4279B MULTI Blood Glucose Monitoring System, FORA Wisdom GD40a / TD-4272A Blood Glucose Monitoring System, FORA Wisdom GD40b / TD-4272B Blood Glucose Monitoring System
- Not intended for use on neonates
- For *in vitro* diagnostic use only
- Allows testing on the fingertip only
- Not for use on patients who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
- Critically ill patients should not be tested with a blood glucose meter.

4. Special instrument requirements:

U- RIGHT TD-4279**A** Blood Glucose Meter (**USB model**)

U- RIGHT TD-4279**B** Blood Glucose Meter (**Bluetooth model**)

U-RIGHT TD-4279**A** MULTI Blood Glucose Meter (**USB model**)

U-RIGHT TD-4279**B** MULTI Blood Glucose Meter (**Bluetooth model**)

FORA GD 40a/TD-4272A Blood Glucose Meter (**USB model**)
 FORA GD 40b/TD-4272B Blood Glucose Meter (**Bluetooth model**)
 FORA Wisdom GD 40a/TD-4272A Blood Glucose Meter (**USB model**)
 FORA Wisdom GD 40b/TD-4272B Blood Glucose Meter (**Bluetooth model**)

I. Device Description:

The U-Right TD-4279 Blood Glucose Monitoring Systems (4 different models, see section H.4. above) and FORA GD40/TD-4272 Blood Glucose Monitoring Systems (4 different models, see section H.4. above) consist of:

- Glucose meter
- Test strips
- One bottle control solution (Level 2) is included in the U-RIGHT TD-4279 A/B kit only. Additional control solutions (Levels 1 and 3) may be purchased separately. Controls were cleared previously in k093724.
- Code strip
- Quick start user guide
- Daily log book
- Warranty card
- Batteries

J. Substantial Equivalence Information:

1. Predicate device name(s):
 TaiDoc, FORA G31A/B Blood Glucose Monitoring System
2. Predicate k number(s):
 k094005
3. Comparison with predicate:

Item	Proposed Devices		Predicate device FORA G31A/B (k094005)
	U-Right TD-4279A/B	FORA GD40a/b/ TD-4272A/B	
Similarities			
Intended use	In the quantitative measurement of glucose in fresh capillary and venous whole blood	Same	Same
Detection method	Amperometry: current produced by chemical reaction	Same	Same
Test range	20 to 600 mg/dL	Same	Same

Altitude	10,742 ft (3,275m)	Same	Same
Operating conditions	50 -104 °F (10°C – 40°C), below 85% R.H.	Same	same
Test time	5 sec	Same	Same
PC data transmission	Model AUSB cable Model B Bluetooth	Same	Same
Memory feature	1000 measurements	Same	Same
Differences			
Capillary Testing sites	finger only	Same as U-Right TD-4279	finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the tight.
Enzyme	Glucose Dehydrogenase (FAD)	Same as U-Right TD-4279	Glucose Oxidase
Test Strip Chemical Components	- Glucose dehydrogenase 8% - Electron shuttle 55% - Enzyme protector 8% - Non-reactive ingredients 29%	Same as U-Right TD-4279	- Glucose oxidase (<i>A. niger</i>) 13% - Electron shuttle 39% - Enzyme protector 6% - Non-reactive ingredients 42%
Hematocrit	20 % – 70 %	Same as U-Right TD-4279	20% - 60%
Test sample	Whole blood from fingertip and venous blood (Capillary for home-use and capillary and venous for professional-use)	Same as U-Right TD-4279	Whole blood from fingertip, palm, forearm, upper-arm, calf and tight
Coding function	Automatic calibration by code strip	Same as U-Right TD-4279	No coding
Code number	Displayed	Same as U-Right TD-4279	Not displayed
Sample volume	1.1 µl	Same as U-Right TD-4279	0.5 µl
Storage conditions	35.6°F- 89.6°F (2°C - 32°C)	Same as U-Right TD-4279	39.6°F- 89.6°F (4°C - 32°C)

	below 85% R.H.)		below 85% R.H.)
Size L x W x H (mm)	94.9 X 52 X 15	94.9 X 52 X 15	85 X 52 X 15
Weight	67.6 g	71 g	95 g

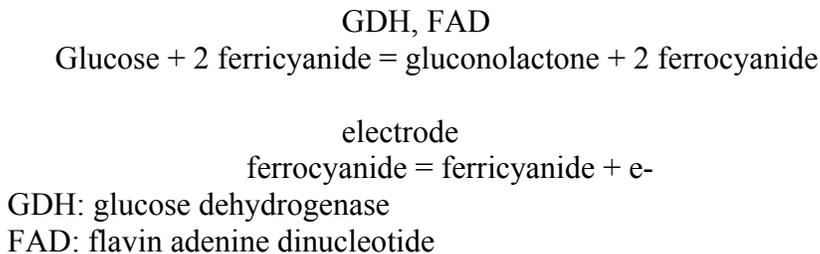
K. Standard/Guidance Document Referenced (if applicable):

- ISO 14971:2007. Medical devices-Application of risk management to medical devices.
- ISO 15197. *In vitro* diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- EN 60601-1-1. Medical electrical equipment, Part 1-1. General requirements for safety. Safety requirements for medical electrical systems.
- EN 60601-1-2:2001 (A1:2006). Medical electrical equipment, Part 1-2. General requirements for basic safety and essential performance. Electromagnetic Compatibility.
- EN 61326-1:2006. Electrical equipment for measurement, control, and laboratory use. EMC Requirements. General requirements.
- IEC/EN 61010-2-101:2002. Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 2-101. Particular requirements for *in vitro* diagnostic (IVD) medical equipment.

L. Test Principle:

The U-Right TD-4279 and FORA GD 40 glucose meters, in conjunction with the same test strips (U-Right TD-4279 or FORA GD-40), utilize amperometric technology to quantitatively measure the glucose concentration in whole blood samples and in control solutions. A glucose dehydrogenase sensor based on the carbon electrode adopting the amperometric assay utilizes the enzyme glucose dehydrogenase to catalyze the formation of gluconolactone from the oxidation of glucose whereby two electrons are produced. Through the mechanism of the mediator, electrical current is generated and it is proportional to the quantity of glucose in the sample.

The reaction principle of reagent depends on following reaction equation:



M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

The sponsor performed precision studies in accordance with the ISO 15197 and CLSI EP-5A. Since the U-Right TD-4279A and U-Right TD-4279B are identical devices as well as FORA GD40 A and FORA GD40 B, which differ only in data transmission function (A - USB model; B - Bluetooth model), the precision studies were performed to evaluate precision of the glucose meters with more complex data transmission function, the U-Right TD-4279B and FORA GD40 B models. The within-run precision study was performed using venous whole blood samples, with hematocrit ranging from 38% to 54%, and dextrose spiked to create 7 levels of blood glucose. Three lots of test strips and 10 meters were used in the study, with 10 tests performed on each meter for a total of 300 tests per blood glucose level. Results for each test strip lot are summarized in the tables below:

Within Day:
 U-Right TD-4279
 Lot 1

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	22.9	1.87	8.17
Level 2	100	39.4	2.25	5.71
Level 3	100	90.5	2.67	2.96
Level 4	100	142.5	4.7	3.30
Level 5	100	178.5	6.34	3.55
Level 6	100	310.3	13.97	4.5
Level 7	100	576.2	13.66	2.37

Lot 2

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	21.4	1.61	7.52
Level 2	100	33.9	1.87	5.52
Level 3	100	87.0	3.18	3.65
Level 4	100	134.1	5.75	4.29
Level 5	100	176.3	6.45	3.55
Level 6	100	307.2	10.63	3.46
Level 7	100	582.6	14.99	2.57

Lot 3

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	21.6	1.89	8.75
Level 2	100	38.0	1.48	3.89
Level 3	100	88.6	1.95	2.20
Level 4	100	134.1	5.01	3.74
Level 5	100	176.3	4.41	2.51
Level 6	100	301.01	6.6	2.19
Level 7	100	580.3	15.25	2.63

FORA GD40:

Lot 1

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	24.4	1.50	6.14
Level 2	100	35.7	2.58	7.23
Level 3	100	93.0	3.44	3.70
Level 4	100	129.2	2.85	2.21
Level 5	100	197.7	6.87	3.48
Level 6	100	367.7	6.87	1.87
Level 7	100	578.7	16.82	2.91

Lot 2

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	24.6	1.37	5.57
Level 2	100	37.3	3.29	8.82
Level 3	100	93.1	2.58	2.77
Level 4	100	132.8	4.71	3.54
Level 5	100	198.4	8.99	4.53
Level 6	100	368.4	8.99	2.44
Level 7	100	579.3	15.42	2.66

Lot 3

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	23.3	1.89	8.11
Level 2	100	37.8	3.12	8.25
Level 3	100	94.8	3.25	3.43
Level 4	100	132.8	3.51	2.65
Level 5	100	198.3	9.28	4.69
Level 6	100	368.4	9.92	2.69
Level 7	100	578.4	16.54	2.86

In addition, the sponsor also evaluated day-to-day precision using venous samples with 6 glucose concentrations collected in commercially available sodium-heparin tubes. Three lots of test strips and 10 meters were used in the study, with 1 test performed on each meter per day for 10 days, for a total of 100 tests per control level. Results for each test strip lot are summarized in the tables below:

Between Day:
U-Right TD-4279:
Lot 1

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	22.6	1.68	7.43
Level 2	100	36.4	2.25	6.18
Level 3	100	115.5	2.67	2.32
Level 4	100	370.3	13.97	3.77
Level 5	100	430.3	13.97	3.25
Level 6	100	591.3	14.21	2.4

Lot 2

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	21.9	2.15	9.82
Level 2	100	30.9	1.87	6.05
Level 3	100	112.0	3.18	2.84
Level 4	100	367.2.4	10.63	2.89
Level 5	100	427.2	10.63	2.49
Level 6	100	581.4	19.37	3.33

Lot 3

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	21.9	2.21	10.09
Level 2	100	35.0	1.48	4.23
Level 3	100	113.6	1.95.6	1.72
Level 4	100	361.6	6.6	1.83
Level 5	100	421.0	6.6	1.57
Level 6	100	588.6	18.98	3.22

FORA GD40:

Lot 1

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	23.5	2.10	8.94
Level 2	100	33.0	3.44	10.42
Level 3	100	121.2	2.85	2.36
Level 4	100	317.7	6.87	2.16
Level 5	100	386.3	8.08	2.09
Level 6	100	589.9	16.34	2.77

Lot 2

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	24.2	2.61	10.79
Level 2	100	33.1	2.58	7.79
Level 3	100	124.8	4.71	3.77
Level 4	100	318.4	8.99	2.82
Level 5	100	385.3	8.89	2.31
Level 6	100	585.3	13.12	2.24

Lot 3

Samples	Number of Tests	Mean (mg/dL)	Standard Deviation (mg/dL)	Coefficient of variation (%)
Level 1	100	24.5	2.29	9.35
Level 2	100	34.8	3.25	9.33
Level 3	100	124.8	3.51	2.82
Level 4	100	318.4	9.92	3.12
Level 5	100	383.1	7.59	1.98
Level 6	100	598.8	12.59	2.10

b. *Linearity/assay reportable range:*

The sponsor performed linearity studies using adjusted whole blood samples with 11 different glucose concentrations covering the measuring range entirely and using both devices, U-Right TD-4279 (B model) and FORA GD40 (B model) and the YSI-2300 glucose analyzer (reference method). Three lots of test strips were used in the study with 20 tests per lot performed on each meter. Linear regression analysis for each test strip lot is summarized below:

U-Right TD-4279:

Lot 1 $y = 0.9833x + 6.2548, r^2 = 0.9974$

Lot 2 $y = 0.9734x + 7.5126, r^2 = 0.9981$

Lot 3 $Y = 0.9707x + 8.0857, r^2 = 0.9952$

FORA GD40:

Lot 1 $y = 1.0339x - 0.5722, r^2 = 0.9944$

Lot 2 $y = 1.0109x + 2.1511, r^2 = 0.9952$

Lot 3 $Y = 1.0089 + 5.2186, r^2 = 0.9879$

The measuring range of the U-Right TD-4279 and FORA GD40 is 20 - 600 mg/dL.

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

The method comparison was performed using the proposed devices and YSI 2300 glucose analyzer.

Controls: Control solutions were cleared in k093724. The control ranges are listed on the test strip vial labels.

The storage claims for these devices are: 90 days for open vial of strips stored at 35.6 – 89.6 °F (2 – 32 °C) and 18 months for unopened vials of strips stored at the same temperature. The study protocol, data and acceptance criteria were provided and found to be adequate.

Temperature and humidity studies: Temperature and humidity studies were conducted on each type of meter (U-Right TD-4279 and FORA GD40) with venous blood samples spanning the measuring range and demonstrating that these devices can be used at temperatures of 4 to 40°C and at a relative humidity up to 85%. The study protocol, data and individual bias of ± 10% across the entire measuring range were provided and found to be adequate.

Open-vial-in-use test strip studies were performed at the combined extremes of 10±2°C (46.4-56.3°F) RH: 30 %, 10±2°C RH:85%, 40±2°C (100.4-107.6°F) RH:30 %, and 40±2°C RH:85% with venous blood samples with concentrations across the measuring range and compared to the YSI. The study protocol, data and individual bias of ±10% across the entire measuring range were provided and found to be adequate.

d. *Detection limit:*

The measuring range of the devices is 20-600 mg/dL. This range was validated via the linearity study (see section M.1.b.).

e. *Analytical specificity:*

The sponsor performed interference studies with spiked venous blood samples at two glucose concentrations (100 and 300 mg/dL) that were prepared and divided into a test (dosed) pool and a control pool. The interferents were added to the sample and each sample was analyzed in duplicate using 4 U - Right TD-4279 and FORA GD40 glucose meters. The table below lists all substances tested at concentrations with insignificant (<10%) interference:

Substance	Concentration with <10% interference (mg/dL)
Acetaminophen	5
Acetylsalicylic acid	50
Acyclovir	3.1
Allopurinol	5
Amitriptyline	0.25
Amoxicillin	11
Ampicillin	5
Ascorbic acid	4
Aspirin	60
Atenolol	10
Bicarbonate	336 mM
Bile acids	6
Bilirubin	20
Caffeine	10
Calcium	5 mM
Chloride	140 mM
Cholesterol	500
Clonidine	2
Creatinine	5
Digoxin	0.16
Diphenhydramine	1
Dopamine	1.25
Enalapril	0.15
Erythromycin	20
Estrone	0.1
Famotidine	0.13
Fluoxetine	0.8
Fructose	1000

Furosemide	2
Galactose	1000
Gentisic acid	2
Glyburide	1.07
Hemoglobin	500
Heparin	6800 U/dL
Ibuprofen	55
Lactose	1000
L-dopa	0.7
Lidocaine	6
Magnesium	5 mM
Mannitol	1000
Mannose	250
Maltose	1000
Metaproterenol	1.81
Methyl-dopa	0.625
Metoprolol	0.3
Naproxen	100
Nifedipine	0.17
Nortriptyline	0.15
Penicillin	12
pH	6.85 – 10.35
Phenytoin	10
Piroxicam	5
Potassium	10 mM
Pralidoxime	5
Sodium	200 mM
Sorbitol	1000
Sulfamethoxazole	120
Sulfate	5 mM
Terfenadine	0.45
Tetracycline	4
Theophylline	25
Tolazamide	6.25
Tolbutamide	64
Total protein	12000
Triglycerides	2000
Urea	600
Uric acid	10
Vancomycin	25
Verapamil	0.45
Vitamin E	20
Warfarin	2
Xylose	6.25

Hematocrit Study:

A study to evaluate the effect of hematocrit was conducted on samples with 8 glucose concentrations at 11 hematocrit levels (20, 25, 30, 35, 40, 45, 50, 55, 60, 65 and 70%). Each glucose level/hematocrit combination was tested in duplicate of 6 of each type of meter (U-Right TD-4279 and FORA GD40) using one lot of test strips. Results of samples at each hematocrit level were compared to samples with the same glucose concentration at normal (40%) hematocrit as well as to the corresponding YSI value. All individual results for each meter type were $\pm 15\%$ of the YSI, supporting the claimed hematocrit range of 20-70%.

- f. *Assay cut-off:*
Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor conducted a combined accuracy and consumer study. Testing was performed at 3 sites, with trained operators and a total of 146 lay-users. Each lay user participant performed their own fingerstick and tested their blood on the U-Right TD-4279 and FORA GD40 (TD-4272) meters using only the instructions in the user's manual and test strip insert. A trained operator then performed a second fingerstick and tested the blood on the same meter. Venous blood was also collected and measured on an YSI analyzer. The total range of samples tested was 32-539 mg/dL for the U-Right TD-4279 meter and 32 to 512 mg/dL for the FORA GD40 (TD-4272) glucose meter. Samples <40 mg/dL and >400 mg/dL were glycolyzed or spiked, respectively, and tested by trained operators as well as lay users. Linear regression results are presented below:

U-Right TD-4279:

Professional vs YSI $y = 1.0452x + 2.2323, r^2 = 0.9954$

Lay user vs. YSI $y = 1.0701x - 2.0936, r^2 = 0.9951$

FORA GD40 (TD-4272):

Professional vs YSI $y = 1.0644x - 3.4426, r^2 = 0.9574$

Lay user vs. YSI $y = 1.0819x - 7.6905, r^2 = 0.9680$

The study results met the ISO 15197 accuracy criteria where ninety-five percent (95%) of the individual glucose results fell within ± 15 mg/dL of the YSI results at glucose concentrations <75 mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL.

For glucose concentrations <75 mg/dL

U-Right TD-4279	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Professionals	23/24 (96%)	24/24 (100%)	24/24 (100%)
Lay user	16/24 (67%)	24/24 (100%)	24/24 (100%)

For glucose concentrations ≥ 75 mg/dL

U-Right TD-4279	within ± 5 %	within ± 10 %	Within ± 15 %	within ± 20 %
Professionals	26/122 (21%)	108/122 (89%)	122/122 (100%)	122/122 (100%)
Lay user	32/122 (26%)	101/122 (83%)	122/122 (100%)	122/122 (100%)

For glucose concentrations <75 mg/dL

GD 40/ TD-4272	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Professionals	21/24 (88%)	24/24 (100%)	24/24 (100%)
Lay user	22/24 (92%)	24/24 (100%)	24/24 (100%)

For glucose concentrations ≥ 75 mg/dL

GD 40/ TD-4272	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Professionals	100/122 (82%)	113/122 (93%)	122/122 (100%)	122/122 (100%)
Lay user	81/122 (67%)	113/122 (93%)	122/122 (100%)	122/122 (100%)

b. Matrix comparison:

Venous blood samples:

Testing was done comparing venous blood samples previously collected in commercially available sodium-heparin tubes and then evaluated with the U-Right TD-4279 and FORA GD40 against YSI-2300. 100 subjects were tested by professionals. Samples from 25 to 560 mg/dL for the U-Right TD-4279 BGM and 22 to 584 mg/dL for the FORA GD40 were included in this analysis. Each fresh capillary whole blood sample used was from a different individual except for samples with blood glucose concentrations less than 40 mg/dL and greater than 400 mg/dL. For those specimens, a pooled capillary whole blood specimen was either glycolyzed or spiked to the desired level. Linear regression results are presented below:

U-Right TD-4279: $y = 0.9912x + 0.6364, r^2 = 0.9826$

FORA GD40/TD-4272: $y = 0.9769x + 2.0365, r^2 = 0.9803$

The study results met the ISO 15197 accuracy criteria where ninety-five percent (95%) of the individual glucose results fell within ± 15 mg/dL of the YSI results at glucose concentrations < 75 mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL.

For glucose concentrations < 75 mg/dL

	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
U-Right TD-4279	15/20 (75%)	20/20 (100%)	20/20 (100%)
FORA GD40 (TD-4247)	11/20 (55%)	19/20 (95%)	20/20 (100%)

For glucose concentrations ≥ 75 mg/dL

	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
U-Right TD-4279	28/80 (35%)	68/80 (93%)	78/80 (98%)	80/80 (100%)
GD 40/ TD-4272	33/80 (41%)	63/80 (88%)	76/80 (95%)	80/80 (100%)

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:

In the labeling the sponsor presents expected blood glucose levels for people without diabetes (referenced from the American Diabetes Association, Clinical

Practice Recommendations. (2010). Diabetes Care, Vol. 33, Supplement 1, p. S1-S100.

Time	Range (mg/dL)	Range (mmol/L)
Fasting and before meals	Less than 100mg/dL	5.6mmol/L
Two hours after meals	Less than 140 mg/dL	7.8 mmol/dL

N. Instrument Name:

- U- RIGHT TD-4279A Blood Glucose Meter (USB model)
- U- RIGHT TD-4279B Blood Glucose Meter (Bluetooth model)
- U-RIGHT TD-4279A MULTI Blood Glucose Meter (USB model)
- U-RIGHT TD-4279B MULTI Blood Glucose Meter (Bluetooth model)
- FORA GD 40a/TD-4272A Blood Glucose Meter (USB model)
- FORA GD 40b/TD-4272B Blood Glucose Meter (Bluetooth model)
- FORA Wisdom GD 40a/TD-4272A Blood Glucose Meter (USB model)
- FORA Wisdom GD 40b/TD-4272B Blood Glucose Meter (Bluetooth model)

O. Systems Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

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

Yes X or No (CLEVER CHECK Health Care System Software cleared under k070941)

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

Yes X or No

2. Software:

FDA 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:

Professionals may test capillary and venous blood, while home-use is limited to capillary whole blood testing only.

5. Calibration:

These systems need to be calibrated every time users open a new vial of test strips. Calibration of the test strip is done by inserting the code strip into the meters when opening a new vial of test strips

6. Quality Control:

The sponsor has three levels of controls that may not be provided with the meters, but can be purchased separately. When a test strip is inserted into the meter, each control can be measured by following the instructions for “Performing a Control Solution Test” provided in the User’s Manuals for the meters. An acceptable range for each control level is printed on the test strip vial label. If the test results fall outside the range printed on the test strip vial, the user is instructed to contact the Customer Care Line at 1-866-469-2632 for customer support. The Customer Care service is available 24 hours a day, 7 days a week, 365 days a year.

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

1. These devices are intended for single-patient use (U- RIGHT TD-4279A/B and FORA GD 40a/b/TD-4247A/B) and multiple patient use/healthcare professional use (U- RIGHT TD-4279A/B MULTI and FORA Wisdom GD 40a/b/TD-4247A/B). Cleaning and disinfection are different processes. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), disinfection is the process of killing germs (e.g. bacteria and viruses). Disinfection studies (viral efficacy studies) were performed by an outside service to evaluate the virus elimination effectiveness of disinfecting wipes in preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV). Specifically, **Micro-Kill+** cleaner disinfectant towels (with EPA registration # 59894-10-37549) were validated demonstrating complete inactivation of live virus. The sponsor does not market a lancing device for use with the device. The sponsor also performed robustness studies using all 4 glucose meters claimed in this 510(k) application (U- RIGHT TD-4279A, U- RIGHT TD-4279B, FORA GD 40a/TD-4247A and FORA GD 40b/TD-4247B) and demonstrated that there was no change in performance or in the external materials of the meters after 10,000 cleaning and disinfection cycles designed to simulate 5 years (5 cleaning and disinfection cycles per day) of single patient device use or 3 years (9 cleaning and disinfection cycles per day) of healthcare professional use. The tested number of cycles is estimated by 5 cleaning and disinfection cycles per day over 5 years, the expected life of the single patient device or 9 cycles per day for the multiple patient use in professional settings. In addition, the sponsor provided a risk analysis specific to the potential harm due to infection. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.

2. Lay-User Study for USB and Bluetooth mediated Data Transmission:

This study was performed using 50 study participants, following instructions in

User's manual, who were able to transmit results from the meter to the PC application (cleared under k070941) via either the USB (25 study subjects) or Bluetooth (25 study subjects) features. The study participants also completed a questionnaire in response to whether the data transmission feature is easy to use. The sponsor concluded that the users' responses indicated that data transmission function was easy to operate by following the User's manuals for both the USB and the Bluetooth mediated data transmission.

3. Altitude study: An altitude study was performed in an altitude simulation chamber with whole blood samples spanning the range of ~20 to 600 mg/dL for both, U-Right TD-4279 and FORA GD40 glucose meters. The study protocol, data and bias $\pm 10\%$ across the entire measuring range were provided and found to be adequate. Altitude up to 10,742 feet (3,275m) does not affect test results of the U-RIGHT TD-4279 and FORA GD40 glucose meters.

4. Specimen volume study: A study was performed to evaluate the effect of different sample volumes (0.8, 0.9, 1.0, 1.1, 1.2, 2.0 and 2.5 μl) on the performance of these devices. It was determined that the 1.1 μl volume of sample provides accurate reading for both, U-RIGHT TD-4279 and FORA GD40 glucose meters. The results from this study for the sample volume of 1.1 μl were within $\pm 10\%$ individual bias across the entire measuring range when U-RIGHT TD-4279 and FORA GD40 measurements were compared to the YSI-2300.

5. The sponsor provided a readability study and obtained Flesch-Kincaid grade level scores of 8 or lower for the User's Manual and test strip insert.

6. Lay user questionnaire: 146 lay users evaluated the ease of use of the device and the presentation of the labeling. All users thought that the U-Right TD-4279 and FORA GD40 Blood Glucose Monitoring Systems were easy to use and most answer "easy" and "very easy" that the user manuals were written to make it easy to use.

7. Additional electromagnetic interference study was performed to verify these new products. The results of this study complied with standards listed in the Standard/Guidance Document Referenced section above. Electromagnetic Compatibility (EMC): EMC testing for u-Right TD-4279 and FORA GD40 was performed/passed and a certificate to TaiDoc was provided.

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.