

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

A. 510(k) Number:

k124040

B. Purpose for Submission:

Modification to cleared meter for outer casing design, software modifications to support data transmission of the cleared meter (k101631). Test strip and software for measurement have not changed.

C. Measurand:

Capillary Whole Blood Glucose

D. Type of Test:

Quantitative, electrochemical biosensor, glucose dehydrogenase FAD

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

ForaCare GD20 Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21CFR Sec.-862.1345 Glucose test system.

2. Product code:

NBW - system, test, blood glucose, over the counter

LFR - glucose dehydrogenase, glucose

3. Classification:

Class II

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

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

2. Indication(s) for use:

The ForaCare GD20 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh whole blood samples (from the finger, palm, forearm and upper arm.). It is intended for use by a single person and should not be shared.

The ForaCare GD20 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 monitoring the effectiveness of diabetes control. It should not be used for the diagnosis of or screening for diabetes, or for testing of neonates. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The ForaCare GD20 test strips are for use with the ForaCare GD20 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, forearm and upper arm.

3. Special conditions for use statement(s):
 - For in vitro diagnostic use only
 - For over-the-counter use
 - For single-patient use only
 - Not intended for use on neonates
 - Not for the diagnosis of or screening for diabetes mellitus
 - Not for use on patients who are dehydrated, hypotensive, in shock, or for individuals in hyperglycemic-hyperosmolar state, with or without ketosis.
 - Not for use in critically ill patients
 - AST results should not be used to calibrate a continuous glucose monitor (CGM) or in insulin dose calculations
4. Special instrument requirements
ForaCare GD20 Blood Glucose Meter

I. Device Description:

The systems consist of three main components: the meter (modified), test strips (previously cleared in k101631), and control solutions (previously cleared in k101631).

The system consists of FORA GD20 meter, FORA GD20 test strips (sold separately), FORA control solutions Level 1, Level 2 and Level 3 (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 glucose in fresh capillary whole blood 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):
U-RIGHT TD-4252 Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k101631
3. Comparison with predicate:

Item	Predicate device	Proposed device
Brand name	U-RIGHT TD-4252 Blood Glucose Monitoring System	ForaCare GD20 Blood Glucose Monitoring System
Model no	TD-4252	GD20
Similarities		
Device	U-RIGHT TD-4252D (k101631)	ForaCare GD20

Item	Predicate device	Proposed device
<p>Indications for use</p>	<p>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.</p> <p>This system is intended to be used by a single person and should not be shared.</p> <p>The U-RIGHT TD-4252 test strips are for use with the</p>	<p>Same as predicate</p>

Item	Predicate device	Proposed device
	<p>U-RIGHT TD-4252 meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from fingertips, palm, forearm and upper arm.</p> <p>Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).</p>	
Detection mechanism		
Detection method	Amperometry:	Same as predicate
Specifications		
Temperature compensation	Automatic compensation with built-in thermistor	Same as predicate
Sample volume (μL)	0.7 μL	Same as predicate
Reaction time (sec)	7 sec.	Same as predicate
Measurement range	20-600 mg/dL	Same as predicate

Item	Predicate device	Proposed device
Power source	One CR2032	Same as predicate
Strip Ejection	Yes	Same as predicate
Hematocrit effect	20% to 60%	Same as predicate
Operation condition	50 °F to 104°F (10 °C to 40 °C), 10% to 85% RH	Same as predicate
Functions		
Power saving	Auto turn-off after 3 minutes without action	Same as predicate
Calibration	No coding required	Same as predicate
Temperature unit	°F	Same as predicate
Measurement mode	General and QC (quality control)	Same as predicate
QC test stored in memory	No	Same as predicate
Day Average	7,14,21,28,60,90 Days	Same as predicate
Test Strip		
Enzyme	Glucose dehydrogenase FAD	Same as predicate
Detection method	Amperometry	Same as predicate
Blood Volume	0.7 µL	Same as predicate
Reaction time	7 Sec	Same as predicate

Item	Predicate device	Proposed device
Strip Storage/ Transportation condition	35.6°F - 89.6°F (2°C - 32°C), 10% to 85% R.H.	Same as predicate
Differences		
Device	U-RIGHT TD- 4252D (K101631)	ForaCare GD20
Functions		
Data transmission function	No	RS232-4 Poles
Measurement unit	mg/dL or mmol/L	mg/dL
Physical appearance		
Outer casing	M button, C button, Set button, LENS, Top cover, Bottom cover, Ejection	M button, C button, Set button, LENS, Top cover, Bottom cover, Ejection button, data
Size (mm) Length X width X height	89.6(L) x53.8 (W) x16.1(H)	87 (L) x 51 (W) x 15 (H)
Weight (g)	40.6g	42g

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

ISO15197:2003, In Vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety 1: Collateral Standard: Safety Requirements

IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for

safety- Collateral standard: Electromagnetic compatibility

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

L. Test Principle:

The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose dehydrogenase. The FORA GD20 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):

Modifications do not impact analytical performance established in k101631 and therefore complete performance testing was not required.

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision includes intermediate precision (day-to-day precision) and repeatability (within-day precision). For intermediate precision, three levels of glucose control solutions were used, and this evaluation was performed for ten days. Repeatability was performed with spiked venous blood samples. Mean, SD and CV% of each of 3 lots was reported. Overall mean, SD and CV% was also calculated. SD and 95% confidence interval (CI) for the SD of each glucose level is reported for glucose concentration levels < 75 mg/dL. CV% of each glucose level is reported for glucose concentration levels ≥ 75 mg/dL.

Results of intermediate precision

	Control Solutions								
	Low level (30-50 mg/dL)			Normal level (96-144 mg/dL)			High level (280-420 mg/dL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean	40.5	41.0	40.8	130.5	132.2	131.0	316.2	315.1	317.8
SD	1.70	1.56	1.59	3.89	3.91	4.17	10.13	9.98	10.10
CV	4.19%	3.82%	3.89%	2.98%	2.96%	3.18%	3.20%	3.17%	3.18%
Overall mean	40.8			131.2			316.5		
Overall SD	1.61			4.03			10.03		
Overall CV	3.95%			3.07%			3.17%		

Results of repeatability precision

	Level 1 (30-50 mg/dL)			Level 2 (51-110 mg/dL)			Level 3 (111-150 mg/dL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean	42.3	42.5	41.8	80.3	80.7	79.8	134.7	136.4	135.5
SD	1.70	1.72	1.85	2.41	2.43	2.30	4.08	4.23	4.21
CV	4.0%	4.04%	4.43%	3.03%	3.01%	2.88%	3.03%	3.10%	3.10%
Overall mean			42.1			80.2			135.5
Overall SD			1.78			2.37			4.18
Overall CV			4.23%			2.96%			3.09%

	Level 4 (151-250 mg/dL)			Level 5 (251-400 mg/dL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
Mean	232.2	230.4	233.3	348.9	352.3	348.3
SD	6.58	6.59	6.60	10.50	10.41	10.71
CV	2.84%	2.86%	2.83%	3.01%	2.95%	3.08%
Overall mean			232.1			349.7
Overall			6.63			10.60

SD						
Overall CV			2.86%			3.03%

- b. Linearity/assay reportable range:*
Linearity was established in k101631. The reportable range is 20-600 mg/dL
- c. Traceability, Stability, Expected values (controls, calibrators, or methods):*
Controls and test strips were previously cleared. Traceability and Stability for controls and test strips were previously established in k101631
- 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.
- d. Detection limit:*
The reportable range is 20-600 mg/dL based on linearity established in k101631.
- e. Analytical specificity:*
As established in k101631
- f. Assay cut-off:*
Not applicable
2. Comparison studies:
- a. Method comparison with predicate device:*
As established in k101631.
- System level verification of accuracy was tested only to establish the modifications being made to the device has not adversely impacted performance.
- Testing was performed for venous whole blood testing using criteria per ISO 15197. The YSI 2300 Glucose Analyzer (YSI Inc., Yellow Spring, OH) was used as the plasma comparative method to matched whole blood tested on the

ForaCare GD20 Blood Glucose Monitoring System. The range of glucose values tested was from 32.7 to 563 mg/dL; and 180 samples were distributed throughout the range per ISO 15197 illustrated below.

Glucose Concentration (mg/dL)	Total distribution (n= 180)	
	Percentage of Samples %	Number of Samples
< 50	5.0%	9
50 to 80	15.0%	27
80 to 120	20.0%	36
120 to 200	30.0%	54
201 to 300	15.0%	27
301 to 400	10.0%	18
>400	5.0%	9

The tables below illustrate 100% of the results agreed within 20% of the YSI plasma values at glucose concentrations ≥ 75 mg/dL, while 100% agreed within ± 15 mg/dL at glucose concentrations < 75 mg/dL, meeting ISO 15197 acceptance criteria.

Results less than 75 mg/dL

Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
8 / 26 (30.8%)	22 / 26 (84.6%)	26 / 26 (100%)

Results greater than or equal to 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
71 / 154 (46.1%)	136 / 154 (88.3%)	149 / 154 (96.8%)	154 / 154 (100%)

- b. *Matrix comparison:*
As established in k101631

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):
As established in k101631
4. Clinical cut-off:
Not Applicable
5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
2 hours after meals	<140 mg/dL

American Diabetes Association (2012) Clinical Practice Recommendations; Diabetes Care, 35 (Supplement 1): S1-100

N. Instrument Name:

ForaCare GD20 Blood Glucose 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 or No

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

device using wireless transmission?:

Yes or No

2. Software:

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

Yes 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:

This device is intended to be used with capillary whole blood from the finger and other alternative sites (palm, forearm, upper-arm, calf and thigh). Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:

Auto-coding.

6. Quality Control:

FORA control solutions Level 1, Level 2 and Level 3 (sold separately) can be run with the ForaCare GD20 Blood Glucose Monitoring System. This meter has 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. Applicable temperature and humidity studies; sample volume study; Altitude study; hematocrit study were established in k101631
2. System level verification was performed to demonstrate that modifications have not adversely affected device performance.
 - a. Temperature and humidity were verified as compared to YSI.
 - b. Quality Control current board (QC board) was conducted to evaluate the accuracy of 10 meters of the modified Foracare GD20 between the dynamic range of 10-700 mg/dL. The QC board is designed to simulate 6 levels of glucose concentration: 10, 50, 100, 200, 400 and 700 mg/dL when connected with the meter, it will send an electrical current to the meter equivalent to the total amount of charge generated by the glucose oxidation reaction at a certain glucose concentration. The meter then process the current and display it in mg/dL unit. Testing passed acceptance criteria.
3. The labeling contains the following contact information: 1-866-469-2632 (toll-free 24 hours, 7 days/week)
4. The applicant performed human factors testing to assess the use of "ForaCare Health Care System Software" for the data transmission feature of GD20 meter. The study evaluated the usability of the software on 30 participants of basic computer skills. The evaluations, including the usability of downloading and set-up of the software on the PC, operating the data transmission from the meter to the software, and questionnaire survey after the test, have demonstrated the accuracy of the activity completion rate was 100% that the software and the data transmission are easy to use by the users.
5. Bench testing using 3 meters was conducted that demonstrated the accuracy of data transmission from the meter to the data management system software is 100% with respect to meter memory rollover and data transmission.
6. Electromagnetic Compatibility (EMC) testing was performed and was certified as passing testing criteria.

7. The applicant provided software documentation and testing that supports that the device was developed and is under good software lifecycle processes.
8. Infection Control Studies: The device is intended for single-patient use. Disinfection efficacy studies were performed on the materials comprising the meter by outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) (Duck) with the chosen disinfectant Micro-Kill+ (EPA Registration # 59894-40-37549). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for each of the meters after 5000 cleanings and 5000 disinfection steps with Micro-Kill+, using two separate wipes for each cleaning and disinfection cycle. The robustness studies were designed to simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.
9. The applicant assessed Foracare GD20 Blood Glucose Monitoring System's labeling, including Owner's manual and Test strip user's manual and obtained a grade level of 7.9 using the Flesch-Kincaid method.

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.