

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

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

k094005

**B. Purpose for Submission:**

Modifications to a previously cleared device (k090187) that include: a. USB or Bluetooth mediated data transmission; b. no-coding; c. increased memory capacity; d. name change; and e. change in size and weight

**C. Measurand:**

Capillary whole blood glucose

**D. Type of Test:**

Whole blood glucose concentration through a quantitative amperometric assay (Glucose Oxidase)

**E. Applicant:**

TaiDoc Technology Corporation

**F. Proprietary and Established Names:**

FORA G31a/TD-4256A Blood Glucose Monitoring System  
FORA G31b/TD-5256B Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:  
21 CFR § 862.1345 Glucose Test System
2. Classification:  
Class II (assay)
3. Product code:  
NBW, Blood Glucose Test System, Over-the-Counter  
CGA, Glucose Oxidase
4. Panel:  
Clinical Chemistry (75)

**H. Intended Use:**

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

2. Indication(s) for use:

FORA G31a/TD-4256A:

FORA G31a/TD-4256A is intended for in vitro use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative testing sites in the FORA G31a/TD-4256A Blood Glucose Monitoring system can be used only during steady-state blood glucose conditions.

FORA G31 and TD-4256 Blood Glucose Test Strips are used with the FORA G31a/TD-4256A glucose meter in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the alternative sites specified above.

FORA Control Solutions/Taidoc Control Solutions are intended for use with the FORA G31a/TD-4256A Blood Glucose meter to check that both the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

FORA G31b/TD-4256B:

FORA G31b/TD-4256B is intended for in vitro use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative testing sites in the FORA G31a/TD-4256A Blood Glucose Monitoring system can be used only during steady-state blood glucose conditions.

FORA G31 and TD-4256 Blood Glucose Test Strips are used with the FORA G31b/TD-4256B glucose meter in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the alternative sites specified above.

FORA Control Solutions/Taidoc Control Solutions are intended for use with the FORA G31a/TD-4256B Blood Glucose meter to check that both the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

3. Special conditions for use statement(s):

- Not intended for diagnosis of diabetes mellitus
- Not intended for use on neonates

- For *in vitro* diagnostic use only
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients
- Allows testing on the fingertip, palm, forearm, upper arm, calf or thigh
- Alternative site testing (AST) can be used only during steady-state glucose conditions, as specified below and in user manuals for FORA G31a/ TD-4256A and FORA G31b/TD-4256B Blood Glucose Monitoring Systems
  - Two hours or more after taking insulin
  - Two hours or more after exercise

4. Special instrument requirements:  
 FORA G31a/TD-4256A Blood Glucose Meter  
 FORA G31b/TD-4256B Blood Glucose Meter

**I. Device Description:**

FORA G31/TD-4256 Blood Glucose Monitoring System consists of two models:

1. FORA G31a/TD-4256A (glucose meter with the USB mediated data transmission)
2. FORAG31b/TD-4256B (glucose meter with the Bluetooth mediated data transmission)

Each of the glucose monitoring systems listed above consists of:

- Glucose meter
- Lancing device
- User manual

Test strips, lancets, and two levels of control solutions, Normal and High (cleared in k041107) are not included with the meter and are available separately.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
FORA G30 Blood Glucose Monitoring System
2. Predicate K number(s):  
k090187
3. Comparison with predicate:

Item	Proposed Devices		Predicate device FORA G30 (k090187)
	FORA G31a or TD-4256A	FORA G31b or TD-4256B	
<b>Similarities</b>			
Intended use	In the quantitative measurement of glucose in fresh capillary whole blood from the	same	same

	<p>finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative site testing in the FORA G30 Blood glucose monitoring system can be used only during steady-state blood glucose conditions.</p>		
Test Strip Chemical Components	<ul style="list-style-type: none"> <li>- Glucose oxidase (<i>A. niger</i>) 13%</li> <li>- Electron shuttle 39%</li> <li>- Enzyme protector 6%</li> <li>- Non-reactive ingredients 42%</li> </ul>	same	same
Test range	20 to 600 mg/dL	same	same
Hematocrit	20 % – 60 %	same	same
Altitude	10,744 ft	same	same
Operating conditions	10°C – 40°C, 85% R.H.	same	same
Temperature range (operational)	10 to 40 °C	same	same
Test time	5 sec	same	same
Sample volume	0.5 µl	same	same
Test sample	Fingertip, palm,	same	same

	forearm, upper arm, calf and thigh		
Differences			
PC data transmission	USB cable	Bluetooth	RS232
Coding function	No coding	No coding	One code function
Memory feature	1000 measurements	1000 measurements	450 measurements
Size L x W x H (mm)	94.9 X 52 X 15	94.9 X 52 X 15	85 X 52 X 15
Power supply	Two AA batteries	Two AA batteries	One CR2032 battery

**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 FORA G31/TD 4256 Blood Glucose Monitoring Systems use electrochemical methodologies. The systems quantitatively measure blood glucose levels using an amperometric method, which involves detecting the current produced from glucose oxidation. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

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

1. Analytical performance:

a. *Precision/Reproducibility:*

Established in the original submission (k090187)

Since the FORA G31a/TD-4156A and FORA G31b/TD-4256B are identical devices which differ only in data transmission function, the new precision

studies were performed to evaluate precision of the glucose meter with more complex data transmission function, the FORA G31b/TD-4256B model. The sponsor evaluated within run precision of the FORA G31b/TD-4256B using a protocol based on ISO 15197. The within-run precision study was performed using venous whole blood samples, with hematocrit ranging from 38% to 54%, and dextrose spiked to create 5 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 100 tests per blood glucose level. Results for each test strip lot are summarized in the tables below:

Within Day precision:

Lot 1

<b>Samples</b>	<b>Number of Tests</b>	<b>Mean (mg/dL)</b>	<b>Standard Deviation (mg/dL)</b>	<b>Coefficient of variation (%)</b>
Level 1	100	39.8	1.86	4.68
Level 2	100	77.3	3.13	4.05
Level 3	100	118.0	4.20	3.56
Level 4	100	203.5	4.47	2.20
Level 5	100	304.1	6.93	2.28

Lot 2

<b>Samples</b>	<b>Number of Tests</b>	<b>Mean (mg/dL)</b>	<b>Standard Deviation (mg/dL)</b>	<b>Coefficient of variation (%)</b>
Level 1	100	39.6	1.56	3.95
Level 2	100	74.7	2.99	4.01
Level 3	100	118.8	3.54	2.98
Level 4	100	204.4	5.75	2.81
Level 5	100	299.7	6.59	2.20

Lot 3

<b>Samples</b>	<b>Number of Tests</b>	<b>Mean (mg/dL)</b>	<b>Standard Deviation (mg/dL)</b>	<b>Coefficient of variation (%)</b>
Level 1	100	39.7	1.85	4.66
Level 2	100	75.8	3.18	4.19
Level 3	100	120.3	2.64	2.20
Level 4	100	203.7	3.82	1.88
Level 5	100	304.0	7.13	2.35

In addition to the new study described above, the sponsor also evaluated day-to-day precision using samples with Low, Medium and High glucose concentrations. 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:

Lot 1

<b>Samples</b>	<b>Number of Tests</b>	<b>Mean (mg/dL)</b>	<b>Standard Deviation (mg/dL)</b>	<b>Coefficient of variation (%)</b>
Low Control	100	82.7	2.06	2.49
Medium Control	100	146.0	3.83	2.62
High Control	100	334.9	4.82	1.44

Lot 2

<b>Samples</b>	<b>Number of Tests</b>	<b>Mean (mg/dL)</b>	<b>Standard Deviation (mg/dL)</b>	<b>Coefficient of variation (%)</b>
Low Control	100	81.5	2.75	3.38
Medium Control	100	146.4	2.98	2.03
High Control	100	334.9	5.76	1.72

Lot 3

<b>Samples</b>	<b>Number of Tests</b>	<b>Mean (mg/dL)</b>	<b>Standard Deviation (mg/dL)</b>	<b>Coefficient of variation (%)</b>
Low Control	100	81.6	2.53	3.10
Medium Control	100	145.9	2.56	1.75
High Control	100	334.8	5.66	1.69

*b. Linearity/assay reportable range:*

Established in the original submission (k090187)  
The measuring range of the system is 20 - 600 mg/dL.

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

Test strips are stable for 12 months when stored between 4°C and 40°C. In-use stability for the test strips is 90 days after the first opening (established in the original, k090187 submission).

In-use stability of the glucose control solutions is 90 days after the first opening when stored between 2 – 30°C (established in the original, k090187 submission).

d. *Detection limit:*

Established in the original submission (k090187)

e. *Analytical specificity:*

Established in the original submission (k090187)

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.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Established in the original submission (k090187)

**Reference Method Comparison:**

In addition, a new method comparison study was performed to demonstrate the accuracy of the proposed devices when compared to measurements obtained with the YSI 2300. One hundred twenty blood samples with glucose concentrations ranging from 24.8 to 594 mg/dL and hematocrit of 38 % to 58% were tested using the FORA G31b/TD-4256B model. Fresh capillary whole blood samples from study participants ranged from 40 mg/dL to 400 mg/dL. Samples with glucose concentrations less than 40 and greater than 400 mg/dL were obtained by spiking the samples to desired concentrations. The study results met the ISO 15197 accuracy criteria where ninety-five percent (95%) of the individual glucose results shall fall within  $\pm 15$ mg/dL of the reference method results at glucose concentrations  $< 75$ mg/dL and within  $\pm 20\%$  at glucose concentrations  $\geq 75$ mg/dL.

Linear Regression Analysis:

FORA G31 b/TD-4256B (candidate device) vs. YSI:

$$y = 1.0087x - 0.5313, r^2 = 0.9966$$

For samples  $< 75$  mg/dL

	Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL

FORA G31 b/TD-4256B	15/19 (79%)	19/19 (100 %)	19/19 (100 %)
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For samples  $\geq 75$  mg/dL

	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
FORA G31 b/TD-4256B	84/101 (83%)	101/101 (100 %)	101/101 (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):*  
Not applicable
4. Clinical cut-off:  
Not applicable
5. Expected values/Reference range:  
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:**

FORA G31a/TD-4256A Blood Glucose Meter  
FORA G31b/TD-4256B Blood Glucose Meter

**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  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 reviewed applicant's Hazard Analysis and software development processes for glucose measurement in k090187. Additionally, in this submission, the sponsor provided data to support the added new features for no-coding, data transmission and memory capacity properties.

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 the alternative sites, such as palm, forearm, upper-arm, calf and thigh, which can be applied directly to the test strip.

5. Calibration:

No calibration is required from the user. The software cleared in k090187 was modified to remove the one code number selection feature and the labeling was modified to reflect the removal of the one code feature.

6. Quality Control:

The sponsor has two levels of controls (cleared under k041107), not provided with the meters, but supplied 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. The FORA G31a/TD-4256A and FORA G31b/TD-4256B have the same basic circuit design. An accuracy test using the Quality Control current board (QC board) was conducted to evaluate if equivalent accuracy can be obtained for those two models

(FORA G31a/TD-4256A and FORA G31b/TD-4256B). Specifically, the QC board was designed to simulate 12 levels of glucose concentration: 20, 40, 60, 80, 100, 120, 160, 200, 280, 400, 550 and 700 mg/dL. The QC board connected to the meter sends electrical current to the meter. The electrical current is equivalent to the total amount of charge generated by the glucose oxidation reaction at a certain glucose concentration. The meter then processes the current and displays it in mg/dL unit. Based on this evaluation, the sponsor concluded that the accuracy of the FORA G31a/TD-4256A Blood Glucose Monitoring System is equivalent to the FORA G31 b/TD-4256B within the specified dynamic range of 20mg/dL to 600mg/dL.

2. The modifications of the new devices when compared to the predicate (parent) device include the addition of USB or Bluetooth mediated data transmission feature from glucose meters to personal PCs, change in the type of coding function, an increase in memory, a name change, and a change in size and weight. The following documentation of these modifications related to software changes was reviewed and found to be acceptable for both glucose meters: level of concern, software description, device hazard analysis, software requirements specifications, software design specification, software development environment description, and verification and validation testing.
3. Lay-User Study for USB and Bluetooth mediated Data Transmission:  
This study was performed with a total of 50 lay users with both the FORA G31a/TD-4256A and FORA G31 b/TD-4256B glucose meters. The 50 study participants, using the information provided in User's manual, were able to obtain testing results, install the PC application and transmit results from the meter to the PC application via either the USB for the FORA G31a/TD-4256A meter or the Bluetooth feature for the FORA G31b/TD-4256B meter. The study participants ranged in age, education, and were about equally divided between males and females. Those study participants also completed a questionnaire in response to whether the data transmission feature is easy to use. The sponsor concluded that the user's 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.
4. The FORA G31/TD 4256 Blood glucose monitoring system operates at 10 to 40°C and relative humidity below 85%. Temperature exposure limits of the system were determined to be -20°C to 60°C, and humidity exposure limits of 5 to 95% relative humidity (see previously cleared k090187). Drop tests and vibration tests were performed on the FORA G31b/TD 4256B Blood glucose monitoring system. These tests support an operating and limit exposure temperature and humidity ranges.
5. Electromagnetic Compatibility (EMC) testing was performed/passed and a certificate to Taidoc Technology Corporation 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.