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

A. 510(k) Number:
k101926

B. Purpose for Submission:
New device

C. Measurand:
Capillary whole blood glucose and blood pressure

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:
There are two proprietary names for the same device intended for:
1. Single patient use: FORA D40d Blood Glucose plus Blood Pressure Monitoring System
2. Multiple patient use: FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1345 Glucose Test System
   21 CFR 870.1130 Noninvasive blood pressure measurement system

2. Classification:
   Class II (assay)

3. Product code:
   NBW, Blood Glucose Test System, Over-the-Counter
   CGA, Glucose Oxidase
   DXN, System, Measurement, Blood-Pressure, Non-Invasive

4. Panel:
   Clinical Chemistry (75) and Cardiovascular

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

2. Indication(s) for use:

1. FORA D40d Blood Glucose plus Blood Pressure Monitoring System

Indications for Use:

The FORA D40d Blood Glucose plus Blood Pressure Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, and upper arm. This system is intended to be used by a single person and should not be shared.

The FORA D40d Blood Glucose plus Blood Pressure 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. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The FORA D40d Test Strips are for use with the FORA D40d Blood Glucose plus Blood Pressure Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, and upper arm.

This system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual at home. The blood pressure is measured by using an inflatable cuff wrapped around the arm.

This system contains speaking function, but is not intended for use by the visually impaired.

2. FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System

Indications for Use:

The FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, and upper arm. This system is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use auto-disabling lancing devices.

The FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System should not be used for the diagnosis of or screening for diabetes, nor for neonatal use. Alternative site testing such as the palm, forearm, and upper arm should be done only during steady – state times (when glucose is not changing rapidly).

The FORA Wisdom D40d Test Strips are for use with the FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, palm, forearm, and upper arm.

This system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual at home. The blood pressure is measured by using an inflatable cuff wrapped around the arm.
This system contains speaking function, but is not intended for use by the visually impaired.

3. Special conditions for use statement(s):
   • For in vitro diagnostic use only
   • Over-the-Counter and Prescription Use

   The following limitations apply to the glucose measurement function:
   • 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.
   • Critically ill patients should not be tested with a blood glucose meter.
   • Allows testing on the fingertip, palm, forearm, upper arm, calf, or thigh
   • Alternative site testing (AST) can be used only during steady-state blood glucose conditions. AST should ONLY be used in the following intervals:
   - In a pre-meal or fasting state (more than 2 hours since the last meal)
   - Two hours or more after taking insulin
   - Two hours or more after exercise
   • Not intended for use by the visually impaired

   The following limitations apply to the blood pressure measurement function:
   • Allows testing only on the arm
   • Not for use in the presence of common arrhythmia

4. Special instrument requirements:
   1. FORA D40d Blood Glucose plus Blood Pressure Meter
   2. FORA Wisdom D40d Blood Glucose plus Blood Pressure Meter

I. Device Description:

This system consists of a glucose meter, arm cuff, user manual, protective wallet, quick start user guide, daily log book, warranty card, and batteries. Control solutions (cleared in k093724) are not included in the kit with the meter and are sold separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   TD-3252 Blood Glucose plus Blood Pressure Monitoring System

2. Predicate k number(s):
   k091555

3. Comparison with predicate:

Item	FORA D40d/FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring Systems	TD-3252 Blood Glucose plus Blood Pressure (k091555)
Blood Glucose Test Principle: Similarities and Differences		
Intended use	The FORA D40d/ **Wisdom D40d** Blood Glucose plus Blood Pressure Monitoring System are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: palm, forearm and upper-arm. It is intended for use by people with diabetes mellitus for a single patient at home as an aid in monitoring the effectiveness of diabetes control. The alternative site testing can be used only during steady-state blood glucose conditions. It is not intended for the diagnosis of or screening for diabetes mellitus, hypertension, or for testing on neonates. The systems are also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual at home. The blood pressure is measured by using an inflatable cuff wrapped around the arm. The systems offer cable and wireless communication function which is able to transmit the test result. It contains speaking function but is not intended for use by the	Same

	visually impaired.	
Enzyme	Glucose Oxidase	Same
Test sample	Whole blood from fingertip, palm, forearm, and upper-arm	Whole blood from fingertip, palm, forearm, upper-arm, calf and thigh
Measuring range	20 – 600 mg/dL	Same
PC connection/ Transmission function	USB and Bluetooth	RS232 and Bluetooth
Reaction time	5 seconds	7 seconds
Code function	No coding	No coding
Storage/Transportation condition	39°F – 104°F (4°C - 40°C), below 85% R.H.	Same
Operation condition	10°C (50°F) to 40°C (104°F), below 85% R.H.	Same
Temperature compensation	Automatic compensation with built-in thermister	Same
Speaking function	Yes	Yes
Strip ejector	Yes	Yes
Earphone port	Yes	Yes
Memory	864 measurements	400 measurements
Measurement mode	General, AC, PC and QC (quality control)	Same
Special message	Lo/Hi/Ketone	Same
Blood Pressure Test Principle: Similarities and Differences		
Detection method	Oscillometry – non-invasive arm measurement	Same
Inflation & Deflation	Automatic control	Same
Maximum inflation pressure	300 mmHg	280 mmHg
Systolic Measurement Range	55 mmHg – 255 mmHg	50 mmHg – 250 mmHg
Diastolic Measurement Range	25 mmHg – 195 mmHg	30 mmHg – 180 mmHg
Pulse rate	40 -199 per minute	Same
Measurement mode	Single measurement and triple measurements for obtaining an average value	Single measurement
Accuracy	Blood pressure: ±3 mmHg or ±2% of reading; Pulse rate: ±4% of reading	Same

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.
- ISO15197:2003 ISO 14971:2000 - Medical devices – Application of risk management

L. Test Principle:

The FORA D40d/FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring uses electrochemical methodologies. This system quantitatively measures 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:*

The sponsor performed precision studies in accordance with the ISO 15197 and CLSI EP-5A. Venous whole blood adjusted to 5 glucose levels with hematocrit ~45% was used for within-day precision studies. Each concentration was tested 10 times each on 10 meters, using 3 test strip lots, for a total of 300 tests per blood glucose level. Results are summarized below:

Within Day precision:

	Level 1			Level 2			Level 3		
Lot	**Average (mg/dL)**	**SD (mg/dL)**	**%CV**	**Average (mg/dL)**	**SD (mg/dL)**	**%CV**	**Average (mg/dL)**	**SD (mg/dL)**	**%CV**
1	42.8	1.86	4.36	80.3	3.13	3.90	146.0	4.20	2.88
2	42.6	1.56	3.67	77.7	2.99	3.85	146.8	3.54	2.41
3	42.7	1.85	4.33	78.8	3.18	4.03	148.3	2.64	1.78

	Level 4			Level 5		
Lot	**Average (mg/dL)**	**SD (mg/dL)**	**%CV**	**Average (mg/dL)**	**SD (mg/dL)**	**%CV**
1	203.5	4.47	2.20	307.1	6.93	2.26
2	204.4	5.75	2.81	302.7	6.59	2.18
3	203.7	3.82	1.88	307.0	7.13	2.32

In addition to the study above, the sponsor also evaluated day-to-day precision using control samples with 3 different levels of glucose. 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 below:

Between Day precision:

	Level 1			Level 2			Level 3		
Lot	**Average (mg/dL)**	**SD (mg/dL)**	**%CV**	**Average (mg/dL)**	**SD (mg/dL)**	**%CV**	**Average (mg/dL)**	**SD (mg/dL)**	**%CV**
1	83.7	2.06	2.46	145.0	3.83	2.64	334.9	4.82	1.44
2	82.5	2.75	3.33	145.4	2.98	2.05	334.9	5.76	1.72
3	82.1	2.45	2.98	144.9	2.56	1.77	334.8	5.66	1.69

b. *Linearity/assay reportable range:*
The sponsor performed linearity studies using whole blood samples with 11 different glucose concentration ranges (from ~10 to ~780 mg/dL). Testing was performed using the FORA D40d/ FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring Systems and the YSI-2300 glucose analyzer (reference method). Three lots of test strips were used in the study. Linear regression analysis for each test strip lot is summarized below:

Lot 1 $y = 0.9621x + 5.6476$, $r^2 = 0.9975$
Lot 2 $y = 0.9514x + 7.1043$, $r^2 = 0.9973$
Lot 3 $y = 0.9605x + 6.0252$, $r^2 = 0.9971$

The measuring range of the FORA D40d/ FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System is 20 - 600 mg/dL.

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

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

Controls: The 3-level control solutions were originally cleared in k093724. However, values of these Control Solutions specific for use with the FORA D40d/ FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring System, were established by repeat analysis using 25 FORA D40d/ FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring devices and 25 corresponding test strips. The mean and standard deviation are used to establish the acceptable range for the strips.

Calibration: no calibration is required by the user.

Stability:
Storage Stability Study: The storage claim for this device is: 90 days for open vial of test strips and controls stored at 39 – 104 ^{o}F (4 – 40 °C) and 24 months for unopened vials of strips and controls stored at 39 – 104 ^{o}F. The study protocols (accelerated testing and real time studies), summary of results and acceptance criteria were reviewed 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 three glucose concentrations (~70, 120 and 300 mg/dL) that were prepared and divided into a test (dosed) pool and a control pool. The potential interferants were added to the sample, tested at least at two concentrations (therapeutic/normal and above therapeutic/toxic) and each sample was analyzed in duplicate using 4 FORA D40d/ FORA Wisdom D40d Blood Glucose plus Blood Pressure Monitoring Systems. The table below lists all substances tested at concentrations with insignificant (<10%) interference:

Substance	**Concentration with <10% interference (mg/dL)**
Acetaminophen	6.25
Acetylsalicilic acid	50
Acyclovir	3.1
Allopurinol	5
Amitriptylline	0.27
Amoxicillin	12.5
Ampicilin	5
Ascorbic acid	5

Aspirin	60
Atenolol	10
Bicarbonate	40 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
K2EDTA	180
K3EDTA	175.5
Erythromycin	20
Estrone	0.1
Ephedrine HCl	60
Famotidine	0.13
Fluoxetine	0.8
Fructose	1000
Furosemide	2
Galactose	250
Gentisic acid	2
Glutathione	23
Glyburide	1.07
Hemoglobin	100
Heparin (Li)	1700 U/dL
Heparin (Na)	1700 U/dL
Ibuprofen	55
Lactose	1000
Lactitole	1000
L-dopa	1.4
Lidocaine	6
Magnesium	5 mM
Maltitole	1000
Maltose	1000
Mannitol	1000
Mannose	250
Metaproterenol	1.81
Methyl-dopa	1.875
Metoprolol	0.3
Naproxen	100

Nifedipine	0.17
Nortriptyline	0.15
Penicillin	12
pH	6.7 – 9.8
Phenytoin	10
Piroxicam	5
Potassium	10 mM
Pralidoxime Iodide	5
Sodium	200 mM
Sorbitol	1000
Sulfamethoxazole	120
Sulfate	5 mM
Terfenadine	0.45
Tetracycline	4
Theophylline	25
Tolazamide	12.5
Tolbutamide	64
Total protein	12000
Triglycerides	2000
Urea	600
Uric acid	10
Vancomycin	25
Verapamil	0.45
Vitamin E	20
Warfarin	2
Xylitol	1000
Xylose	6.25

f. *Assay cut-off:*
Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*
The sponsor conducted a combined accuracy study and consumer study, with trained operators and 150 samples (136 study subjects/natural patient samples + 14 altered samples) comparing accuracy of the candidate device to the YSI 2300 analyzer. The study subjects ranged in age, education, and were about equally divided between males and females. The blood samples with glucose concentrations ranging from 22 to 581 mg/dL were tested. Samples with glucose concentrations less than 40 and greater than 400 mg/dL were either glycolyzed or spiked and tested by trained operators as well as lay-users. Distribution of blood glucose concentration across the samples tested was in accordance with the ISO15197. The studies met the ISO 15197 accuracy

criteria where ninety-five percent (95%) of the individual glucose results shall fall within ±15mg/dL of the results at glucose concentrations <75mg/dL and within ±20% at glucose concentrations ≥75mg/dL. The results relative to YSI are summarized in the tables below:

Trained operators vs. YSI
Linear Regression Analysis:

Finger: $y = 1.004x + 3.8033$, $r^2 = 0.9849$
Palm: $y = 0.9969x + 1.8077$, $r^2 = 0.9801$
Forearm: $y = 1.004x + 3.6933$, $r^2 = 0.9867$
Upper arm: $y = 0.9835x + 6.2784$, $r^2 = 0.9831$

For samples < 75 mg/dL

	Within ± 5 mg/dL	**Within ± 10 mg/dL**	**Within ± 15 mg/dL**
Fingertip	20/26 (77%)	25/26 (96%)	26/26 (100%)
Palm	15/26 (58%)	25/26 (96%)	26/26 (100%)
Forearm	15/24 (54%)	23/24 (96%)	24/24 (100%)
Upper arm	16/25 (64%)	23/25 (96%)	25/25 (100%)

For samples ≥ 75 mg/dL

	Within±5%	**Within±10%**	**Within±15%**	**Within±20%**
Fingertip	64/124 (52%)	100/124 (81%)	120/124 (97%)	124/124 (100%)
Palm	57/124 (44%)	92/124 (73%)	120/124 (97%)	124/124 (100%)
Forearm	55/126 (44%)	92/126 (73%)	119/126 (94%)	126/126 (100%)
Upper arm	48/125 (38%)	87/125 (70%)	121/125 (97%)	125/125 (100%)

Lay-users vs. YSI

Linear Regression Analysis:
Finger: $y = 1.0622x + 0.55771$, $r^2 = 0.9789$
Palm: $y = 1.0427x - 4.9914$, $r^2 = 0.9722$
Forearm: $y = 1.0154x + 1.393$, $r^2 = 0.9747$
Upper arm : $y = 1.0306x - 1.956$, $r^2 = 0.9711$

For samples < 75 mg/dL	**Within ± 5 mg/dL**	**Within ± 10 mg/dL**	**Within ± 15 mg/dL**
Fingertip	13/18 (72%)	17/18 (94%)	18/18 (100%)

Palm	9/18 (50%)	17/18 (94%)	18/18 (100%)
Forearm	11/16 (69%)	15/16 (94%)	16/16 (100%)
Upper arm	8/17 (47%)	16/17 (94%)	17/17 (100%)

For samples ≥ 75 mg/dL

	Within±5%	**Within±10%**	**Within±15%**	**Within±20%**
Fingertip	50/118 (42%)	82/118 (69%)	112/118 (95%)	118/118 (100%)
Palm	38/118 (32%)	78/118 (66%)	113/118 (96%)	118/118 (100%)
Forearm	46/120 (38%)	83/120 (69%)	114/120 (95%)	120/120 (100%)
Upper arm	38/119 (32%)	80/119 (67%)	113/119 (95%)	119/119 (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 100 mg/dL	5.6mmol/L
Two hours after meals	Less than 140 mg/dL	7.8 mmol/dL

N. Instrument Name:
FORA D40d (TD-3216A) Blood Glucose Meter
FORA Wisdom D40d (TD-3216B) 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 ____X_(reviewed under k070941) or No _____

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

5. Calibration:
   No calibration is required by the user. The meter accommodates auto-coding, in that each strip is designed and manufactured to code the meter appropriately when the strip is inserted.

6. Quality Control:
   The sponsor has three levels of controls that are not provided with the device, 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 (FORA D40d) and multiple-patient use (FORA Wisdom D40d). 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 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 of multiple-patient use with cleaning and disinfecting after each patient up to 9 uses per day. 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. Hematocrit Study: A study to evaluate the effect of hematocrit was conducted on samples with 9 glucose concentrations spanning the range of 20-600 mg/dL at 9 hematocrit levels (20, 25, 30, 35, 40, 45, 50, 55, and 60%). Each glucose level/hematocrit combination was tested in duplicates of 6 using one test strip lot. The results from this study were within ±15% individual bias, supporting the claimed hematocrit range of 20-60%. 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 ±15% of the YSI, supporting the claimed hematocrit range of 20-60%

3. Altitude Study: An altitude study was performed in an altitude simulation chamber with whole blood spiked samples spanning the range of ~20 to 600 mg/dL. The device-specific measurements at level 0 ("sea level") were compared to the "high altitude" measurements and to the YSI measurements as well. The study protocol and data were provided, reviewed and found to be adequate. Altitude up to 11500 feet (3500 m) does not affect test results of the FORA D40d/FORA Wisdom D40d Monitoring Systems.

4. Temperature and humidity studies: Temperature and humidity studies were conducted to demonstrate that the FORA D40d/FORA Wisdom D40d Blood Glucose Monitoring Systems can be used at temperatures of 4 to 40°C and at a relative humidity below 85%, and stored at temperatures of 4 to 40°C with a relative humidity below 85%. The FORA D40d test strips are stable for 24 months when stored unopened and 90 days when stored opened at 4 to 40°C with a relative humidity below 85%. The study protocol and data of individual measurements compared to the YSI across the entire measuring range were provided and found to be adequate.

5. Open-vial-in-use test strip studies were performed at the combined extremes of 10±2°C (46.4-56.3°F) and RH: 10 %, 10±2°C RH:85%, 40±2°C (100.4- 107.6°F) RH:10 %, 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 ±10% bias of individual measurements across the entire measuring range when compared to YSI were provided and found to be adequate.

6. A study to evaluate the effect of different sample volumes (0.3, 0.4, 0.5, 0.6, and 1.0µl) was conducted to demonstrate that the 0.5 µl volume provides accurate reading The results from this study for the sample volume of 0.5 µl were within ±10% individual bias across the entire measuring range when FORA D40d/FORA Wisdom D40d measurements were compared to the YSI-2300.

7. Lay-User Study for USB and Bluetooth mediated Data Transmission:
This study was performed as a part of the lay-user study described above in 2.a. The 50 study participants, following instructions in User's manual, were able to transmit results from the meter to the PC application (cleared under k070941) via either the USB or Bluetooth features. 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 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.

8. Lay user questionnaire: 136 lay users evaluated the ease of use of the device and the presentation of the labeling. All users thought that the FORA D40d and FORA Wisdom D40d 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.

9. 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

10. 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) 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.