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

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

k101635

**B. Purpose for Submission:**

Clearance of new device

**C. Measurand:**

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:**

TD-4239 Blood Glucose Monitoring System
TD-4239 Multi Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:

   21 CFR: 862.1345, Blood Glucose Test System

2. Classification:

   Class II

3. Product code:

   NBW, LFR

4. Panel:

75 (clinical chemistry)

## H. Intended Use:

1. Intended use(s):

   Same as indications for use below.

2. Indication(s) for use:

*TD-4239 Blood Glucose Monitoring System*

The TD-4239 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples from the finger. It is intended to be used by a single person and should not be shared.

The TD-4239 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. It is not intended for the diagnosis of or screening for diabetes mellitus or be used on neonates.

The TD-4239 Blood Glucose Test Strips are for use with the TD-4239 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

*TD-4239 Multi Blood Glucose Monitoring System*

The TD-4239 Multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary, venous and neonatal whole blood samples. The TD-4239 Multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple patient use in professional healthcare settings as an aid in monitoring the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus.

Professionals may test with capillary, venous and neonatal whole blood. Capillary samples may be drawn from the fingertip, and in the case of neonates, from the heel.

The system is only used with single-use, auto-disabling lancing devices

The TD-4239 Multi Blood Glucose Test Strips are for use with the TD-4239 Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary, venous and neonatal whole blood samples.

3. Special conditions for use statement(s):

- Not intended for diagnosis of or screening for diabetes mellitus
- For in vitro diagnostic use only
- Not for use on critically ill patients or dehydrated patients

- Not for use on severely hypotensive individuals or patients in shock.

- Not for use on individuals experiencing a hyperglycemic-hyperosmolar state, with or without ketosis.

- For TD-4239 Multi Blood Glucose Monitoring System; only Heparin should be used as an anticoagulant

- The TD-4239 Multi Blood Glucose Monitoring System must be disinfected between users following labeling recommendations.

- Only single use, auto-disabling lancing devices can be used with the TD-4239 Multi Blood Glucose Monitoring System

- The TD-4239 Blood Glucose Monitoring System is not intended for use on neonates.

4. Special instrument requirements:
TD-4239 Blood Glucose meter
TD-4239 Multi Blood Glucose meter

**I. Device Description:**

TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System (glucose meters with the USB mediated data transmission)
The glucose monitoring systems listed above consists of:

- Glucose meter
- Lancets
- User manual
- Test strips
- Fora control solutions cleared under k093724

The differences between the TD-4239 and the TD-4239 Multi Blood Glucose Monitoring System are labeling, which includes disinfection instructions for using the device in multiple patient use settings. The TD-4239 Multi Blood Glucose Monitoring System should only be used with single-use, auto-disabling lancing devices. The Fora control solutions consists of three control levels (1, 2, and 3)

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

   FORA G31 Blood Glucose Monitoring System

2 Predicate 510(k) number(s):

   k094005

3. Comparison with predicate:

| Item | FORA G31 Blood Glucose Monitoring System - Predicate | TD-4239 Blood Glucose Monitoring System | TD-4239 Multi Blood Glucose Monitoring System |
|---|---|---|---|
| Intended Use/Indications for Use | It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes. | Same | Same |
| Sample test time | 5 second | Same | Same |
| Detection method | Amperometry | Same | Same |
| Enzyme | Glucose oxidase | Glucose dehydrogenase | Glucose dehydrogenase- |
| Calibration Coding | Code number is preinstalled and only one code number is assigned. User must choose and insert the correct test trip. | Automatic calibration by code strip because the meter is designed to recognize the code strip and calibrate automatically | Automatic calibration by code strip because the meter is designed to recognize the code strip and calibrate automatically |
| Memory | 1000 measurements | 400 measurements | 400 measurements |
| Test range | 20-600 mg/dL | 20-600 mg/dL | 10-600 mg/dL |
| Hematocrit range | 20-60% | 20-70% | 20-70% |
| Sample type | Fresh capillary and venous whole blood | Fresh capillary whole blood | Fresh capillary, venous and neonatal whole blood |
| Sample sites | Fingertip, palm, the forearm, upper-arm, calf and thigh | Finger tip | fingertip, and in the case of neonates, from the heel. |
| Sample volume | 0.5 uL | 1.1 uL | 1.1 uL |

**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 TD 4239 glucose meters, in conjunction with the same test trips, 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:

$$\text{Glucose} + 2\ \text{ferricyanide} \xrightarrow{\text{GDH, FAD}} \text{gluconolactone} + 2\ \text{ferrocyanide}$$

$$\text{ferrocyanide} \xrightarrow{\text{electrode}} \text{ferricyanide} + e^-$$

GDH: glucose dehydrogenase
FAD: flavin adenine dinucleotide

The glucose biosensors recognize the glucose present in whole blood or control solutions by virtue of the specificity of the enzyme FAD dependent glucose dehydrogenase (GDH) present on the test strip. The electrons liberated by this reaction are transferred via a co-factor and mediator to the meter where they are read as a small electrical current. 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. <u>Analytical performance:</u>

   The TD-4239 and theTD-4239 Multi Blood Glucose Monitoring System are the same meters and test strips, however, they have separate names because of the different

indications for use. All performance studies were conducted using the TD 4239 Blood Glucose Monitoring System.

*a. Precision/Reproducibility:*

The sponsor performed precision studies in accordance with ISO 15197 and CLSI EP-5A. Fresh venous whole blood adjusted to 7 glucose levels (hematocrit 45%) were used for within-day precision studies. Each concentration was tested 10 times each on 10 meters, using 3 test strip lots, (100 total tests divided between 3 strip lots per blood glucose level). Results are summarized below:

Within Day precision (whole blood):

| | Interval 1 (less than 20 mg/dL) | | | Interval 2 (30-50 mg/dL) | | |
|---|---|---|---|---|---|---|
| Test strip Lot | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 |
| Mean | 16.7 | 17.0 | 16.3 | 42.7 | 39.7 | 41.1 |
| SD | 1.06 | 1.36 | 1.02 | 2.00 | 1.62 | 1.73 |
| CV | 6.32% | 8.03% | 6.26% | 4.68% | 4.07% | 4.20% |
| Overall mean | 16.6 | | | 41.2 | | |
| Overall SD (95% CI) | 1.17 ( 0.8 – 1.54) | | | 2.12 (1.73 – 2.5) | | |
| Overall CV | 7.02% | | | 5.14% | | |

| | Interval 3 (51-110 mg/dL) | | | Interval 4 (111-150 mg/dL) | | |
|---|---|---|---|---|---|---|
| Test Strip Lot | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 |
| Mean | 70.9 | 67.0 | 67.1 | 138.3 | 133.9 | 133.4 |
| SD | 1.84 | 1.77 | 2.36 | 4.19 | 3.51 | 3.97 |
| CV | 2.59% | 2.64% | 3.51% | 3.03% | 2.62% | 2.97% |
| Overall mean | 68.2 | | | 135.0 | | |
| Overall SD | 2.71 | | | 4.44 | | |
| CV | 3.97% | | | 3.29% | | |

| | Interval 5 (151-250 mg/dL) | | | Interval 6 (251-400 mg/dL) | | |
|---|---|---|---|---|---|---|
| Test Strip Lot | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 |
| Mean | 206.4 | 197.2 | 202.9 | 321.5 | 313.7 | 315.6 |
| SD | 8.00 | 6.58 | 6.80 | 11.88 | 9.59 | 11.72 |
| CV | 3.87% | 3.34% | 3.35% | 3.70% | 3.06% | 3.71% |
| Overall mean | 202.3 | | | 316.8 | | |
| Overall SD | 7.92 | | | 11.52 | | |
| CV | 3.92% | | | 3.64% | | |

In addition to the study above, the sponsor also evaluated day-to-day precision using control samples with 6 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, (100 total tests divided between 3 strip lots per control level). Results for each test strip lot are summarized in the tables below: Results of intermediate precision: TD 4239

Day to day precision:

| | Low level control solution (less than 20mg/dL) | | | Low level control solution (30-50 mg/dL) | | |
|---|---|---|---|---|---|---|
| Test Strip Lot | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 |
| Mean | 12.6 | 12.3 | 13.1 | 41.7 | 39.9 | 40.0 |
| SD | 2.01 | 1.84 | 1.75 | 1.91 | 1.55 | 1.92 |
| CV | 15.90% | 14.98% | 13.44% | 4.59% | 3.88% | 4.81% |
| Overall mean | 12.7 | | | 40.5 | | |
| Overall SD (95% CI) | 1.87 (1.61 - 2.12) | | | 1.98 (1.56 – 2.40) | | |
| Overall CV | 14.72% | | | 4.89% | | |

| | Normal level control solution (96-144 mg/dL) | | | Mid-high control solution (280-420 mg/dL) | | |
|---|---|---|---|---|---|---|
| Test Strip Lot | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 |
| Mean | 123.6 | 118.8 | 119.5 | 316.2 | 296.5 | 302.5 |
| SD | 4.74 | 4.23 | 3.36 | 8.16 | 9.62 | 7.14 |
| CV | 3.83% | 3.56% | 2.81% | 2.58% | 3.24% | 2.36% |
| Overall mean | 120.5 | | | 304.8 | | |
| Overall SD | 4.53 | | | 11.35 | | |
| CV | 3.76% | | | 3.72% | | |

| | High level control solution (308-460 mg/dL) | | | High level control solution (455-680 mg/dL) | | |
|---|---|---|---|---|---|---|
| Test Strip Lot | Lot 1 | Lot 2 | lot 3 | Lot 1 | Lot 2 | Lot 3 |
| Mean | 416.4 | 417.4 | 408.1 | 590.0 | 589.0 | 594.7 |
| SD | 12.21 | 12.09 | 11.72 | 22.60 | 19.39 | 20.79 |
| CV | 2.93% | 2.90% | 2.87% | 3.83% | 3.29% | 3.50% |
| Overall mean | 413.4 | | | 591.6 | | |
| Overall SD | 12.64 | | | 20.89 | | |
| CV | 3.06% | | | 3.53% | | |

b. Linearity/assay reportable range:

The sponsor performed linearity studies using adjusted venous blood samples with 12 different glucose concentrations ranging from less than 10 to 750 mg/dL for the TD-4239 Blood Glucose Monitoring System. For each level solution, 10 consecutive tests (with 5 measurements per lot) by YSI-2300 and TD-4239 glucose meter were performed respectively. The resulting data was compared and the linear regression analyses were as follows:

TD-4239 Slope =1.0086 y intercept = 1.3961 $r^2 = 0.9992$

The measuring range is 20-600 mg/dL for the TD-4239 Blood Glucose Monitoring System and 10-600 mg/dL for the TD-4239 Multi Blood Glucose Monitoring System and has been shown to be linear within the measuring range.

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

Fora control solutions were cleared under k 093724

The TD-4239 Blood Glucose Monitoring System and TD-4239- multi Blood Glucose Monitoring System (including control solution and strips) have an operating environment of 50-104 degrees F and a relative humidity between 10%-85%. Performance testing conducted under low humidity/ high temperature and vice versa (In-use stability data) support this range.

Test strips were evaluated to determine open and closed vial stability. Data provided by the sponsor supports closed vial stability of TD-4239 test strips for 18 months and open vial stability of 3 months when stored at the recommended conditions of 2º - 32ºC / 35.6º - 89.6ºF, between 10%- 85% R.H.

Calibration: calibration of the test strip is done by inserting the code strip into the meter when opening a new vial of test strips.

d. Detection limit:

The claimed measuring range is 20-60 mg/dL for the TD-4239 Blood Glucose Monitoring System and 10-600 mg/dL for the TD-4239 Multi Blood Glucose Monitoring System

*e. Analytical specificity:*

**Interference Study:**

The sponsor indicated that the interference study protocol was developed according to NCCLS, EP 7-A2. Venous blood was obtained from fasting subjects and collected in a heparin-Na (sodium heparin) vacutainer tube (Hct around 45%).
Two concentrations of glucose were adjusted to 60-80 mg/dL (low) and 150-200 mg/dL (high) using the YSI 2300 as a reference instrument. The glucose samples were spiked with the potentially interfering compounds equivalent to the highest therapeutic dosage and toxic level (or ten times the highest therapeutic concentrations when toxic levels were not known), and tested on 3 lots of test strips. Bias was calculated as the mean percent difference in glucose reading between the test and control concentration groups. All samples tested showed % bias within ± 10% between the test and the control groups. The sponsor claims no significant interference (≤ 10% difference) for the substances and concentrations shown in the table below:

| **Substance** | **Concentration with <10% interference (mg/dL)** |
|---|---|
| Acetaminophen | 5 |
| Acetylsalicilic acid | 50 |
| Acyclovir | 3.1 |
| Allopurinol | 5 |
| Amitriptyline | 0.25 |
| Amoxicillin | 11 |
| Ampicillin | 5 |
| Ascorbic acid | 4 |
| Aspirin | 60 |
| Atenolol | 10 |
| Bicarbonate | 336 |
| Bile acids | 6 |
| Bilirubin | 20 |
| Caffeine | 10 |
| Calcium | 73.5 |
| Chloride as Calcium Chloride | 818.16 |
| 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 |
| 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 | 76.56 |
| Pralidoxime | 5 |
| Sodium | 1168.80 |
| Sorbitol | 1000 |
| Sulfamethoxazole | 120 |
| Sulfate as Ammonium Sulfate | 66.07 |
| 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 |

The sponsor has the following limitations in their labeling:

Xylose: Do not test blood glucose during or soon after an absorption test. Xylose can give falsely elevated results.

There is no significant interference (≤ 10%) in the presence of galactose, maltose, fructose or mannitol observed in blood glucose tests as demonstrated in studies up to 1,000 mg/dL

Lipemic Effects: Blood triglycerides up to 2000 mg/dL (22.8 mmol/L) do not affect the results significantly (≤ 10%), but may affect results at higher levels.

Summary of drugs and concentrations in excess of ≤ 10% interference

| Substance | Limiting Concentration (mg/dL) | Therapeutic / Physiologic Concentration Range (or Upper Limit ) (mg/dL) |
|---|---|---|
| Acetaminophen | > 5 | 0.45 - 3 |
| L – Dopa | > 0.7 | 0.02 - 0.28 |
| Methyl – Dopa | > 0.625 | 0.1 - 0.5 |
| Tolazamide | > 6.25 | 1.6 |
| Mannose | > 250 | 1.15 |
| Dopamine | > 1.25 | 0.03 |
| Xylose | > 6.25 | N/A |
| Pralidoxime Iodide | > 5 | N/A |

*f. Assay cut-off:*

Not Applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

Reference method comparison professional vs. Lay user comparison study for Capillary Blood.

The sponsor states that the study was performed in accordance with ISO 15197.

Testing was completed by comparing the TD-4239 blood glucose monitoring systems against YSI-2300 glucose analyzer (reference method) .The study was conducted at 3 different clinical sites, with a total of 148 subjects. Three lots of test strips were used in the study.

Samples ranging from 15 to 527 mg/dL were included. The fresh capillary whole blood samples from different individuals were used except for blood glucose concentrations less than 40 mg/dL and greater than 400 mg/dL. (12/148) Pooled capillary whole blood samples were spiked and glycolyzed to obtain these concentrations.

Lay users were given the user manual in English for the blood glucose monitoring systems TD-4239 and were given no additional instructions. They were requested to perform the test by themselves and answer the questionnaire. Health care professionals took one further measurement (immediately after) with the TD-4239, and the results between the lay users vs. reference and health care professionals vs. reference were compared. An additional capillary blood sample was taken within 5 minutes and was tested by professionals with the YSI 2300 blood glucose monitoring system for comparison.

**Results**

Difference distribution for glucose concentration <75mg/dL of lay users versus YSI-2300

| | Difference within ±5mg/dL | Difference within ±10mg/dL | Difference within ±15mg/dL |
|---|---|---|---|
| TD-4239 | 17/28 (61%) | 27/28 (96%) | 28/28 (100%) |

Difference distribution for glucose concentration≧75mg/dL

| | Difference within ±5 % | Difference within ±10 % | Difference within ±15 % | Difference within ±20 % |
|---|---|---|---|---|
| TD-4239 | 58/120 (48%) | 104/120 (87%) | 118/120 (98%) | 120/120 (100%) |

Difference distribution for glucose concentration <75mg/dL of healthcare professional versus YSI-2300

| | Difference within ±5mg/dL | Difference within ±10mg/dL | Difference within ±15mg/dL |
|---|---|---|---|
| TD-4239 | 23/28 (82%) | 28/28 (100%) | 28/28 (100%) |

Difference distribution for glucose concentration≧75mg/dL

| | Difference within ±5 % | Difference within ±10 % | Difference within ±15 % | Difference within ±20 % |
|---|---|---|---|---|
| TD-4239 | 69/120 (58%) | 107/120 (89%) | 119/120 (99%) | 120/120 (100%) |

The study met the ISO 15197 standard accuracy criteria where 95% of the individual glucose results fall within ± 15 mg/dL of the results at glucose concentrations < 75 mg/dL and within ± 20% at glucose concentrations ≥ 75 mg/dL.

Regression analyses of lay user and professional accuracy versus YSI-2300

| Comparison | N | Slope and y-intercept | | $R^2$ |
|---|---|---|---|---|
| Lay users vs. YSI-2300 | 148 | TD-4239 | y = 1.0944x – 5.293 | 0.9941 |
| Professional vs. YSI-2300 | 148 | TD-4239 | y = 1.0972x – 7.4474 | 0.9955 |

*b. Matrix comparison:*

**Accuracy for venous whole blood**

The sponsor states that the study was performed in accordance with ISO 15197.

Testing was completed by comparing the TD-4239 blood glucose monitoring systems against YSI-2300 glucose analyzer (reference method). The study was conducted with 100 subjects using fresh venous whole blood using a vacutainer tube containing sodium heparin (10mL). To meet the distribution specified in ISO 15197, for specimens less than 40 mg/dL and greater than 400 mg/dL, the sponsor used a pool of whole blood specimen and it was spiked or glycolyzed to obtain the desired levels pooled whole blood specimen was used and spiked to the desired level.

The range of blood glucose samples used was between 15-597 mg/dL and three lots of test strips were used in the study.

Table below present the glucose value differences of devices versus YSI-2300 with venous whole blood for glucose concentration <75mg/dL.

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| | Difference within ±5mg/dL | Difference within ±10mg/dL | Difference within ±15mg/dL |
|---|---|---|---|
| TD-4239 | 17/20 (85%) | 18/20 (90%) | 20/20 (100%) |

The table below present the glucose value differences of devices versus YSI-2300 with venous whole blood for glucose concentration ≧ 75mg/dL

| | Difference within ±5 % | Difference within ±10 % | Difference within ±15 % | Difference within ±20 % |
|---|---|---|---|---|
| TD-4239 | 39/80 (49%) | 67/80 (84%) | 77/80 (96%) | 80/80 (100%) |

The study met the ISO 15197 standard accuracy criteria where 95% of the individual glucose results fall within ± 15 mg/dL of the results at glucose concentrations < 75 mg/dL and within ± 20% at glucose concentrations ≥ 75 mg/dL

Regression analysis of glucose values

| Reference method | N | Slope and y-intercept | | $R^2$ |
|---|---|---|---|---|
| YSI-2300 | 100 | TD-4239 | y = 1.0206 x + 2.096 | 0.9914 |

**Neonates**

Fresh neonatal blood specimens were obtained from the heel of 140 neonates by healthcare professionals at a general hospital in Taiwan to evaluate clinical accuracy of TD-4239 (as the test method) against YSI-2300 (as the reference method). Blood glucose values were compared and the data was presented in compliance with ISO 15197 standard.

Samples ranging from 12 to 187.6 mg/dL, with hematocrit of 22% to 69% were included. Tables below present the glucose value comparison between the TD- 4239 and the YSI-2300 with neonatal blood

For glucose concentration <75mg/dL:

| | Difference within ±5mg/dL | Difference within ±10mg/dL | Difference within ±15mg/dL |
|---|---|---|---|
| TD-4239 | 27/51(53%) | 49/51(90%) | 51/51(100%) |

For glucose concentration ≧ 75mg/dL:

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| | Difference within ±5 % | Difference within ±10 % | Difference within ±15 % | Difference within ±20 % |
|---|---|---|---|---|
| TD-4239 | 42/89(47%) | 70/89 (79%) | 85/89 (96%) | 89/89 (100%) |

The study met the ISO 15197 standard accuracy criteria where 95% of the individual

glucose results fall within ± 15 mg/dL of the results at glucose concentrations < 75 mg/dL and within ± 20% at glucose concentrations ≥ 75 mg/dL.

Regression analysis of glucose values

| Reference method | N | Slope and y-intercept | | $R^2$ |
|---|---|---|---|---|
| YSI-2300<br>Range: 12-187.6 mg/dL | 140 | TD-4239 | y = 0.9516+ 5.138 | 0.9115 |

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:
   The sponsor provides the following information in the labeling:

   **Reference values:**

| Time of day | Normal plasma glucose range for people without diabetes |
|---|---|
| Fasting and before meal | Less than 100 mg/dL (5.6 mmol/L) |
| 2 hours after meals | Less than 140 mg/dL (7.8 mmol/L) |

   Source: American Diabetes Association (2010). Clinical Practice Recommendations. Diabetes Care, 33 (Supplement 1): S1-S100.

**N. Instrument Name:**

TD-4239 Blood Glucose Monitoring System,
TD-4239 Multi Blood Glucose Monitoring System

**O. System 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 _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission? :
   Yes ___or No __X___

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 fingertip capillary and venous, and neonatal blood, while home-use is limited to fingertip capillary whole blood testing only.

5. Calibration:

   These systems need to be calibrated with the code strip from every new vial of test strips

6. Quality Control:
   Glucose control solutions are cleared under k 093724. The labeling provides instructions on when to test control solutions.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**

1. Altitude: A study was conducted to evaluate the effect of altitude on the TD 4239

BGMS. Same test samples were tested on 4 meters using venous whole blood from healthy donors at eight glucose concentrations (ranging from 20-600mg/dL) at three corresponding altitude levels (5000, 11,500, and 15,000 feet), and sea level (0 feet) as a control. Testing was performed in a hyperbaric chamber (glove box). Each venous blood sample was also tested by the YSI 2300 analyzer. The meter readings obtained were compared to the YSI method and the percent bias was determined at each level against the YSI results. Bias was within ± 10% for all three altitude levels tested. Based on the data, the sponsor claims that the TD 4239 BMGS can be used at altitude up to 15,000 feet.

2. Hematocrit: The sponsor performed hematocrit studies using eleven different hematocrit levels (20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70%) levels across the glucose measuring range (10-600 mg/dL). At each hematocrit level, 8 concentrations of glucose were tested against the YSI method. Test strips from the same lot were tested on 6 meters and the values were compared to the YSI method and the nominal hematocrit level (40%). All results fell within ±10 mg/dL bias at glucose concentrations < 75 mg/dL and within ±10% bias at glucose concentrations ≥ 75 mg/dL against the reference method YSI-2300. Across the entire hematocrit range ( 20-70%) the difference between the candidate and YSI device is within +/- 15%.

3. Temperature and humidity study: The TD-4239 Blood Glucose Monitoring System, operates at 50 -104 $^{o}$F (10$^{o}$C – 40$^{o}$C), and relative humidity between 10%- 85%. The sponsor tested the extreme combinations of temperature and humidity, i.e. lowest and highest temp at lowest and highest humidity. These tests support the operating temperature and humidity ranges.

4. Drop tests and vibration tests were conducted and results analyzed to give the mean, SD and CV before and after the challenge. The sponsor provided the test report to confirm that vibration tests were conducted on 3 meters at random wave form between frequencies of 5- 500 Hz on X Y Z axes, 30 minutes per axis. Results of TD-4239 showed CVs less than 5% at three glucose levels, and the mean difference % before and after challenge were review were reviewed and deemed acceptable.

5. Specimen volume study: A sample volume study was performed to verify the test strip sample volume requirement and the test strip fill error requirement established for the BGMS. Three lots of test strips were tested on Spiked or glycolized venous whole blood (Hct: 45%) with three levels: 1) 33 to 63 mg/dL, 2) 117 to 175 mg/dL, 3) 250 to 376 mg/dL. Blood at each concentration was applied to strips at five target sample volumes of 0.8, 0.9, 0.1.0, 1.1 and 1.2 µL. Protocols and acceptance criteria were provided and found to be acceptable. The sponsor concluded that sample volume of ≥0.9 µL produced accurate results and samples <0.9 µL give an error code.

6. Lay user questionnaire: 150 lay users evaluated the ease of use of the device and the presentation of the labeling. All users thought that the device was easy to use (Very

easy; Easy and Average-100% lay users) and most answer Very easy, Easy and Average that the user manuals were written to make it easy to use.

7. Electromagnetic Compatibility (EMC) testing was performed and passed and a certificate to Taidoc Technology Corporation was provided.

8. Readability testing: For the readability assessment of instruction manuals, the sponsor used Flesch-Kincaid readability analysis to determine the grade level at which the Owner's Manual and strip manual for both proposed devices were written, for is 8th grade reading level.

9. Disinfection and Robustness studies: The device is intended for single-patient (TD-4239 Blood Glucose Monitoring System) or healthcare professional use (TD-4239 Multi Blood Glucose Monitoring System). Disinfection studies were performed on these meters by an outside commercial testing service to determine the robustness of the meter to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of blood borne pathogens, particularly Duck hepatitis B virus (HBV). Micro-Kill Plus™ disposable wipes (EPA Reg. No: 59894-10-37549) were validated, demonstrating complete inactivation of live virus for use with the meter. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after10,000 cleaning and disinfection cycles designed to simulate 3 years of healthcare professional use and 5 years of use by lay users. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.

**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.