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

A. 510(k) Number:

k112963

B. Purpose for Submission:

Modified device (The manufacturer made the following modifications to their predicates: physical appearance, data transmission from RS-232 to Bluetooth and minor software modifications).

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-4257 Blood Glucose Monitoring System
TD-4257 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-4257 Blood Glucose Monitoring System

   The TD-4257 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-4257 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-4257 Blood Glucose Test Strips are for use with the TD-4257 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

   TD-4257 Multi Blood Glucose Monitoring System

   The TD-4257 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-4257 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-4257 Multi Blood Glucose Test Strips are for use with the TD-4257 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-4257 Multi Blood Glucose Monitoring System; only Heparin should be used as an anticoagulant
- The TD-4257 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-4257 Multi Blood Glucose Monitoring System
- Single-patient use devices are for use on single-patients only and should not be shared.
- The TD-4257 Blood Glucose Monitoring System is not intended for use on neonates.

4. Special instrument requirements:

TD-4257 Blood Glucose meter
TD-4257 Multi Blood Glucose meter

I. Device Description:

The TD-4257 Blood Glucose Monitoring Systems/TD-4257 Multi Blood Glucose Monitoring System is supplied as a kit which consists of:
• A glucose meter
• Test strips
• A storage case

Control solutions, and test strips may be supplied separately to the kit. The test strips are identical to the test strips cleared under k101635. The control solutions are cleared under k093724.

The modified device has the same intended use and method of glucose measurement comparing to the predicate (TD-4239 and the TD-4239 Multi Blood Glucose Monitoring System, cleared under k101635). The current devices differ from the predicates in the modification of meter physical appearance and data transmission method from data port to blue tooth.

Users have the option of uploading the stored test results into a personal computer (PC) through a Bluetooth connection with program pre-installed in their PC, Health Care System Software that has received clearance under K070941.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Taidoc, TD-4239 and TD-4239 Multi Blood Glucose Monitoring Systems

2 Predicate 510(k) number(s):

k101635

3. Comparison with predicate:

Item	Predicate devices	Proposed devices
Brand name	TD-4239/ TD-4239 Multi Blood Glucose Monitoring Systems	TD-4257/ TD4257 Multi Blood Glucose Monitoring Systems
Model no	TD-4239	TD-4257
Similarities		
Indications for use (single patient use)	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.	Same
Indications for use (Multi-patient use)	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.	Same

	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.	
Detection mechanism		
Detection method	Amperometry: measuring a current produced by a chemical reaction	Same
Enzyme	Glucose dehydrogenase (FAD-GDH)	Same
Specifications		
Sample volume (μL)	1.1 μL	Same
Reaction time (sec)	5 seconds	Same
Measurement unit	mg/dL	Same
Measurement range	20-600 mg/dL (single patient use) 10-600 mg/dL (Multi-patient use)	Same
Meter Storage/ Transportation condition	-4°F – 140°F (-20℃ - 60℃), below 95% R.H.	Same
Functions		
Power saving	Auto turn-off after 3 minutes without action	Same
Code Display	Code number is displayed on screen.	Same
Measuring mode	General, AC, PC and QC (quality control)	Same
Day average	7-, 14-, 21-, 28-, 60- and 90-day average glucose result	Same
Alarm function	4 alarms	Same
Strip ejection function	Yes	Same
Special message	Lo/Hi/Ketone?	Same
Test Strip Calibration	Automatic calibration by code strip	Same
Test Strip		
Detection method	Amperometry: measuring a current produced by a chemical reaction	Same

Enzyme	Glucose dehydrogenase	Same
Blood Volume	1.1 μL	Same
Reaction time	5 seconds	Same
Strip Storage/ Transportation condition	36°F- 90°F (2°C-32°C) below 85% R.H.	Same
Differences		
Device	TD-4239/ TD-4239 Multi Blood Glucose Monitoring System	TD-4257/ TD4257 Multi Blood Glucose Monitoring System
Size (mm) Length X width X height	95 mm (L) x 49 mm (W) x 14 mm (H)	102mm(L) x 64 mm (W) x 29.5 mm (H)
Weight (g)	42 g (without batteries)	81g (without batteries)
Power source	One 3V CR2032 lithium battery	2 x 1.5V AAA batteries
Backlight	No	Yes
Memory feature	400 measurements	1000 measurements
Transmission Function	Uses RS232 cable to transmit data to computer	Uses Bluetooth to transmit data to computer
User interface	M button, C button, SET button, test strip ejector, data port	M button, SET button, test strip ejector

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.

L. Test Principle:

Same as predicate devices cleared under k101635.

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. Analytical performance:

The current devices differ from the predicates in the modification of meter physical appearance and data transmission method from data port to blue tooth. The modifications do not affect the analytical function of the meter and the current devices use the same test strips as cleared in the predicate devices in k101635.

a. Precision/Reproducibility:

Same as predicate devices cleared under k101635.

b. Linearity/assay reportable range:

The sponsor claims the same measuring range as established for the predicate devices. The sponsor claims 20-600 mg/dL for the TD-4257 Blood Glucose Monitoring System and 10-600 mg/dL for the TD-4257 Multi Blood Glucose Monitoring System.

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

Traceability: Traceable to NIST SRM 91, dry D-glucose.

The control solutions were cleared under k093724.

Test strips were cleared under k101635. 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 ranges are the same as the predicate devices; 20-600 mg/dL for the TD-4257Blood Glucose Monitoring System and 10-600 mg/dL for the TD-4257 Multi Blood Glucose Monitoring System.

e. Analytical specificity:

Interference Study:

Same as predicate devices cleared under k101635.

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.

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. System accuracy as compared to YSI

The system accuracy was evaluated using 126 whole blood samples with glucose concentrations across the measuring range. The distribution of the glucose concentrations in these samples are depicted in the below table:

Glucose Concentration by YSI ng/mL	Number of samples
20-50	21
50-80	21
80-120	21
120-200	21
201-400	21
401-600	21

Each sample was tested in duplicate on three meters and the results are compared to the YSI method.

Result Summary:

Glucose ≤ 75 mg/dL (42 samples)

Number of test result	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
252	100% (252/252)	100% (252/252)	100% (252/252)

Glucose > 75 mg/dL (84 Samples)

Number of test result	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
504	71% (358/504)	100% (504/504)	100% (504/504)

Summary Assessment of Accuracy (126 Samples)

Number of test result	Readings within ±15 mg/dL if <75 mg/dL, ±20% if ≥75 mg/dL
756	100% (756/756)

Conclusion:
The performance of the TD-4257 and the TD-4257 Multi Blood Glucose Monitoring System meets ISO 15197 accuracy requirement of more than 95% results within the acceptance limits of ±15mg/dL if <75 mg/dL or ±20% if ≥75 mg/dL.

b. Matrix comparison:

The data was presented and reviewed in predicate devices cleared in k101635.

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-4257 Blood Glucose Meter,
TD-4257 Multi Blood Glucose Meter

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 __X__ or No ____

2. Software:

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

   Yes __X___ or No

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   Professionals may test 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. An accuracy test using the Quality Control current board (QC board) was conducted to evaluate the accuracy of 10 TD-4257 meters in glucose range of 10-700 mg/dL.

   The QC board is designed to simulate 12 levels of glucose concentration: 10, 20, 40, 60, 80, 100, 120, 160, 200, 280, 400, 550 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.

   The same procedure was also performed on 10 predicate meters of TD-4239. For the current device TD4257, the CV of the mean of 10 meter measurements was between 0.00%-0.40% at the 13 glucose levels. For the predicate meter TD-4239, the CV of the mean of 10 meter measurements was between 0.00%-0.32% at the 13 glucose levels. The sponsor concluded that the accuracy of the modified TD-4257 meter was consistent through out the 13 glucose intervals with CV significantly below the set acceptance criteria of 5%.

2. Altitude:
   The sponsor claims that the TD 4257 BMGS can be used at altitude up to 15,000 feet based on study performed on the predicate device TD4239 in k101635.

3. Hematocrit:
   The sponsor claims a hematocrit range of 20-70% based on study performed on the predicate device TD4239 in k101635.

4. Temperature and humidity:

   The sponsor claims that the TD-4257 meters operates at 50 -104 ^{o}F (10^{o}C – 40^{o}C), and relative humidity between 10%- 85% based on study performed on the predicate meters k101635.

5. Drop tests and vibration tests were conducted. The study protocol and test report were reviewed and deemed acceptable.

6. EMC testing was performed for TD4257 and TD4257 multi Blood Glucose Monitoring Systems by an accredited EMC Testing Laboratory ETC. A test certificate was issued to Taidoc Technology Corporation on December 28, 2009.

7. Disinfection and Robustness studies:
   Due to the casing changes in the new devices as compared to the predicates, new Disinfection and Robustness studies were performed for TD4257 and TD4257 multi Blood Glucose Monitoring Systems.

   The 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 meters. The sponsor also demonstrated that there was no change in performance or in the external materials of the meters and lancing device after 10,000 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.

8. The software changes related to the modified functions (Bluetooth data transmission and memory storage of up to 1000 tests) were tested and the intended functions were validated.

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.