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

A. 510(k) Number:
k091555

B. Purpose for Submission:
Modifications to a previously cleared device that include: the addition of some speaking functions, auto coding function, increased memory capacity, a name change, and a change in size and weight of meter.

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:
TD-3252 Blood Glucose plus Blood Pressure Monitoring System

G. Regulatory Information:

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

2. Classification:
   Class II
   Class I, reserved

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

4. Panel:
   75 Clinical Chemistry
   74 Cardiovascular

H. Intended Use:

1. Intended use(s):
   Refer to indications for use below.

2. Indication(s) for use:
   The TD-3252 Blood Glucose plus Blood pressure Monitoring System is intended for 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. The alternative site testing in this system can be used only during steady-state blood glucose conditions. This system is not intended for use on neonates.

   The 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 a technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 9.4" ~ 13.8".

   This system offers either cable or wireless communication function which is able to transmit the test result to other devices, such as PC or data receiver.

   This monitor has some 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:
   TD-3252 Blood Glucose meter

I. Device Description:

This system consists of a glucose meter, lancing device, arm cuff, and 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.

The addition of voice features affects both the glucose measuring component and the blood pressure measuring component. The modifications to the glucose meter coding function only affect the blood glucose measuring component.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Clever Chek TD-3250C Blood Glucose plus Blood Pressure Monitoring System
2. Predicate 510(k) number(s):
   k080014
3. Comparison with predicate:

Similarities		
Item	Predicate - k080014 (Clever Chek TD-3250C Blood Glucose plus Blood Pressure Monitoring System)	New Device (TD-3252 Blood Glucose plus Blood Pressure Monitoring System)
Enzyme	Same	Glucose oxidase
Anatomical Sites	Same	Fingertip, palm, forearm, upper-arm, calf and thigh
Sample volume	Same	0.7 ul
Reaction time	Same	7 sec
Measurement range	Same	20 – 600 mg/dL

Differences		
Item	Predicate - k080014 (Clever Chek TD-3250C Blood Glucose plus Blood Pressure Monitoring System)	New Device (TD-3252 Blood Glucose plus Blood Pressure Monitoring System)
Size (mm)	137x90x54	152x95x55
Weight (g)	250g without batteries	280g without batteries
Memory	352 measurements results with respective dates and times	400 measurements results with respective dates and times
Some speaking function	No	Yes

Differences		
Item	Predicate - k080014 (Clever Chek TD-3250C Blood Glucose plus Blood Pressure Monitoring System)	New Device (TD-3252 Blood Glucose plus Blood Pressure Monitoring System)
Code function	Users need to calibrate the monitor	Users do not need to calibrate the monitor
Gen/AC/PC/QC record	General mode and control solutions for blood glucose measurement	General, AC, PC and QC mode for blood glucose measurement
Strip-ejection button	No	Yes
Data transmission	RS232/ Zigbee /Bluetooth	RS232/Bluetooth
Up button & Down button	No	Yes
Repeat button	No	Yes
Earphone port	No	Yes

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

- ISO15197:2003 - *In vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- ISO 14971:2000 – Medical devices – Application of risk management to medical devices.
- CLSI EP-9A: Method Comparison and bias estimation using patient samples; Approved Guideline.
- CLSI EP5-A: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.

L. Test Principle:

The glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, producing gluconolactone. The current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Established in the original submission (k062800)

   b. Linearity/assay reportable range:

   Established in the original submission (k062800)

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

The control solutions, Normal and High, with target values of 125 and 300 mg/dL, were originally cleared in k041107.

d. Detection limit:

Established in the original submission (k062800)

e. Analytical specificity:

Established in the original submission (k062800)

f. Assay cut-off:
Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Established in the original submission (k062800).

In addition, a new method comparison study was performed with 120 capillary fingerstick samples where the participants tested themselves. The range of glucose concentrations of the samples was 31 – 548 mg/dL by the reference method (YSI-2300). The glucose concentrations less than 40 and greater than 400 mg/dL were obtained by spiking the samples to desired concentrations. The linear regression line for the accuracy study was, y = 1.014x – 1.228, r = 0.997. Using the ISO 15197 format the following were obtained:

<75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
19/21 (90%)	21/21 (100%)	21/21 (100%)

≥75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
88/99 (89%)	95/99 (96%)	97/99 (98%)	98/99 (99%)

b. Matrix comparison:
Not applicable. Only capillary whole blood samples can be used with this meter.

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):

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   The sponsor includes the following Expected Values for people without diabetes in their glucose strip labeling:

   _____

   Status Range
   Fasting and before meals[1] 70-110 (mg/dL) (3.9-6.1 mmol/L)
   2 hours after meals[2] Less than 140 mg/dl (7.8 mmol/L)

   _____

   Sources:
   [1]Tietz Textbook of Clinical Chemistry, 1999
   [2]American Diabetes Association Clinical Practice Recommendations, 2003

N. Instrument Name:
TD-3252 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 each additional reading.
2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
   Yes ___X___ or No _____
   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 ____.

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, upper-arm, calf and thigh 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:
   There are two levels of control (Normal and High) not supplied with the device. Users are instructed to test control solutions when the meter is first used in order to verify that they can use the meter correctly. In addition they are instructed to run a control when a new vial of test strips is opened, when they suspect the meter or strips are not working correctly, if test results appear to be abnormally high or low, or are not consistent with the patient's symptoms, if the meter is dropped, to check their technique, if the test strip bottle had been left open or stored outside its recommended temperature range, and each time the batteries are changed.

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

The sponsor performed a readability assessment of the labeling and states that the user manual is written at an 8th grade level.

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.