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

A. 510(k) Number:

k061073

B. Purpose for Submission:

New Device

C. Measurand:

Glucose and Blood Pressure

D. Type of Test:

Quantitative Glucose Oxidase

Blood Pressure – Non-invasive Oscillometric

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

TaiDoc Clever Check TD-3250 Blood Glucose and Blood Pressure Measurement System.

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1345, Glucose Test System
   21 CFR §862.1660, Quality Control Material (assayed and unassayed)
   21 CFR §870.1130, Noninvasive blood pressure measurement system

2. Classification:

   Class II (Glucose Test System)
   Class I, reserved (Assayed Quality Control Materials)
   Class II (Blood Pressure Measurement System)

3. Product code:

   NBW, CGA – Glucose Test System
   JJX – Single (specified) analyte controls (assayed and unassayed)
   DXN – Blood Pressure Measurement System

4. Panel:

   75, Clinical Chemistry – Glucose Test System and Quality Control Material
   74, Cardiovascular – Blood Pressure Measurement System

H. Intended Use:

1. Intended use(s):

   See Indications for use below.

2. Indication(s) for use:

   The Clever Chek TD-3250 Blood Glucose and Blood Pressure Measurement System is intended for in vitro diagnostic use. The system is intended to be used for the quantitative measurement of capillary whole blood from the finger. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a 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 system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 16, at home by using a technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 9.4 inches to~ 13.8 inches.

3. Special conditions for use statement(s):

   This device is not intended to diagnose or screen for diabetes mellitus, and is not to be used on neonates. The sample site is fingertip only. The device is for in vitro diagnostic use, over-the-counter and professional use.

4. Special instrument requirements:

   TaiDoc Clever Chek TD-3250 Glucose and Blood Pressure System

I. Device Description:

The device combines the function of a blood glucose meter and a blood pressure measurement system in one unit. Supplies with the meter are the test strips, code strip (included in each test strip vial), lancets, lancet holder, storage case control solutions,

operator's manual, package inserts and quick reference guide. To measure blood glucose, the user first inserts the code strip into the meter. When the numerical code appears on the display screen the user confirms that the number on the display, code strip and the test strip vial match. Once the user confirms that the numbers match, glucose testing can proceed. The user inserts a test strip and then applies a blood drop to the test strip. The meter initiates the test which completes in ten seconds. Results are stored in the meters memory for tracking purposes. The lancet supplied with the device was previously cleared under k833344. The two control solutions supplied with the device were previously cleared under k012430.

To mesure blood pressure, the user is instructed to connect the pressure cuff to the device. Next the user wraps the cuff around the upper arm with the palm facing up approximately 0.8 to 1.2 inches above the elbow. The user is instructed not to speak or move during the measurement. Instructions are provided explaining how to perform a test correctly. The results are stored in the meter's memory for tracking purposes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Achtung TD-4207 Blood Glucose System, TaiDoc Technology Corporation
   BpTRU Automated Non-invasive Blood Pressure Monitor, BP-100, VSM Technology Inc.

2. Predicate 510(k) number(s):

   k042005 and k012636, respectively.

3. Comparison with predicate:

Similarities – Glucose Meter		
Item	Device	Predicate
Specimen	Same	Capillary Whole Blood
Methodology	Same	Electrochemical, Glucose Oxidase
Measuring Range	Same	20 -600 mg/dL
Display	Same	Direct Readout; no calculation required
Sample volume	Same	2 uL
Test Time	Same	10 seconds

Differences – Glucose Meter		
Item	Device	Predicate
Number of readings Stored in Memory	352	450
Size	137*90*54	80*60*20
Power Source	Four 1.5V AA batteries	CR2032 3V lithium batteries

Similarities – Blood Pressure Monitoring System		
Item	Device	Predicate
Type of Reading	Same	Non-invasive, diastolic and systolic blood pressure and pulse rate
Pulse Rate	40-200 beats/min	40-200 beats/min
Stethoscope	Same	Not Required
Power Source	Same	Two AAA batteries

Differences – Blood Pressure Monitoring System		
Item	Device	Predicate
Measuring Range	0-300 mm Hg	0-290 mm Hg
Target Population	Age 16 and above	Age 3 and above
Maximum Cuff Pressure	300 mmHg	330 mmHg

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

CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

CLSI EP6-P2; Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Proposed Guideline

CLSI/NCCLS EP7-P; Interference Testing in Clinical Chemistry; approved Guideline

EN 60601-1 / 1990 /1998 / 2001; Medical electrical equipment - Part 1: Particular general requirements for the safety

EN 61010-1 / 2001; Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: general requirements

EN 61010-2-101 / 2002 Particular requirements for in vitro diagnostic (IVD) medical equipment

L. Test Principle:

Glucose: glucose oxidase in the strips reacts with the glucose in the sample producing an electrical current which is proportional to the glucose concentration. The meter measures the current and converts it to the corresponding glucose concentration in mg/dL or mmol/L.

Blood pressure: the pressure sensor in the cuff detects small changes in pressure and converts them to electrical signals. The meter analyzes the singles and converts them to standard measurements of systolic and diastolic blood pressure and pulse rate.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor evaluated the intra precision of the device by assaying 5 spiked whole blood specimens of different concentrations (30-400 mg/dL) in one run, using 10 meters and three lot numbers of test strips. The results are presented in the table below:

Over all mean, SD and CV for three test strip lots

	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
N	300	300	300	300	300
Mean	52.2	76.0	114.2	246.8	314.5
SD	2.47	2.41	4.21	6.24	4.98
CV%	4.74	3.17	3.69	2.53	1.58

The inter precision (between day) was evaluated by assaying 3 control solutions of different concentrations (60-400 mg/dL) once a day for 10 days using 10 meters and three lot numbers of test strips. The results are presented in the table below:

Over all mean, SD and CV for the three test strip lots

	Low Control	Normal Control	High Control
N	300	300	300
Mean	75.6	131.8	322.6
SD	1.54	3.38	5.33
CV%	2.04	2.56	1.65

b. Linearity/assay reportable range:

The linearity of the glucose measurements was demonstrated by comparing blood samples on the TaiDoc 3250 glucose meter and the glucose reference method (YSI). The nine samples ranged in concentration from a low approximately 20 mg/dL to a high of approximately 600 mg/dL.

The linear regression of the data yielded the following relationship:

$y = 0.995x + 4.1825$, $R^2 = 0.9993$

The reportable range for glucose measurements is 20-600 mg/dL

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

The controls supplied with this device were previously cleared under k012430.

d. Detection limit:

20 mg/dL – see linearity section above M.1.b

e. Analytical specificity:

Specificity of the glucose meter was assessed by spiking various endogenous and exogenous compounds into prepared whole blood samples. The sponsor first prepared a low whole blood control at approximately 80 mg/dL and a high whole blood control at approximately 300 mg/dL glucose and confirmed these concentrations prior to the addition of the interferents. The sponsor then added the interfering substance and assayed each control solution on the TaiDoc 3250 system. If the change in glucose measurement from the control solution was less the 10% this was considered no interference. Results of the testing were as follows:

Interferent	Highest Concentration With < 10% Interference	
	Low Glucose Control (80mg/dL)	High Glucose Control (300mg/dL)
Acetaminophen	5 mg/dL	5 mg/dL
Ascorbic Acid	2.25 mg/dL	3 mg/dL
Dopamine	2 mg/dL	2 mg/dL
L-dopa	3 mg/dL	3 mg/dL
Methyldopa	0.5 mg/dL	0.75 mg/dL
Tolbutamide	200 mg/dL	200 mg/dL
Triglycerides	2000 mg/dL	2000 mg/dL
Uric Acid	10 mg/Dl	10 mg/dL

The meter was tested at different altitudes to assess the effect of low oxygen levels on the meter performance. No effect on performance was found when three different levels of controls were tested at 10,000 ft. Higher elevations were not tested.

The sponsor presented data that supported using the test system between 10ºC to 40ºC.

Hematocrit Effect:

The effect of sample hematocrit variation on the TaiDoc 3250 system was tested experimentally by preparing samples of known hematocrit and spiking aliquots of these samples with six different levels of glucose. These samples were assayed on the TaiDoc and YSI. The results showed less than a $\pm$20% bias at glucose concentrations $\geq$75 mg/dL and less than a ±15 mg/dL bias at glucose concentrations <75 mg/dL across the claimed range of 20~60% Hematocrit.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

One hundred and twenty (120) capillary blood samples were collected and assayed on the TD-3250 system and then assayed on the predicate device (TD-4207). Three lots of test strips were tested; two replicates were performed for a total of 240 fingerstick readings. The sample range was from 20-594 mg/dL. The resulting linear regression is as follows:

TD-3250 result 1 vs. TD-4207 result 1 – $y = 0.969x + 3.0$; $R = 0.9949$

TD-3250 result 2 vs. TD-4207 result 2 – $y = 0.995x – 4.2$; $R = 0.9922$

Accuracy was based on the ISO International Standard 15197. One hundred and twenty fingerstick samples were assauyed on the TD-3250 and compared to a reference method (TSI). Acceptable accuracy for results was stated as: 95% of the individual results shall fall within ±15 mg/dL at glucose concentration <75 mg/dL and within 20% at glucose concentration ≥75 mg/dL. Results are shown in the tables below:

Accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
20/40(50%)	32/40 (80%)	40/40 (100%)

Accuracy results for glucose concentration ≥75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20%
91/200 (46%)	158/200 (79%)	184/200 (92%)	195/200 (98%)

b. Matrix comparison:

Not applicable. The glucose meter is intended to be used with capillary whole blood from the finger only.

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):

The consumer study was performed with a total of 120 lay-users. The lay-users ranged in age, education and were about equally divided between males and females. Each participant performed their own fingerstick and tested their blood using the instructions in the User's guide. A trained professional then performed another fingerstick and tested the blood on the same meter and reference device.

	Number of samples	TD-3250 vs. reference device	r value	Sample Range (mg/dL)	% Error Grid	
					A	B
Lay-user	120	y = 1.013-3.141	0.976	52-456	98%	2%
Professional	120	y = 0.966+5.809	0.990	50-431	100%	

4. Clinical cut-off**:**

Not Applicable.

5. Expected values/Reference range:

The normal fasting adult glucose range for a non-diabetic is 80-120 mg/dL (4.5-6.7 mmol/L. One – Two hours after a meal, normal blood glucose results should be less the 180 mg/dL (<10 mmol/L). A medical professional should determine the range that is appropriate for diabetes patients.

N. Instrument Name:

TaiDoc Clever Chek TD-3250 Blood Glucose and Blood Pressure Measurment System

O. System Descriptions:

1. Modes of Operation:

Single use device for the test strips. There are no disposable components used to measure blood pressure.

2. Software:

   FDA has 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 only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

   A code strip is supplied with each vial of test strips to calibrate the meter for the vial. No further calibrations are required of the user.

6. Quality Control:

   The sponsor is providing a normal and high glucose solution with this device. After inserting the test strip press the M (memory) key, "CtL" will be displayed and the control mode is activated. This prevents the control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. If the control results fall outside these ranges, the user is referred to a list of troubleshooting steps and a customer care number.

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

The following comments are based on a consultant review from the Division of Cardiovascular Device. The review was only for the blood pressure portion of this device.

The device is said to be in compliance with EN 60601-1-1, General Requirements for Safety and EN 60601-1-2, Electromagnetic Compatibility.

The manufacturer has provided software validation test protocols and results of testing which

indicates how well the software handles problems. Also, they provided reliability testing to 10,000 cycles as well as tables indicating applicable conformance to the ANSI/AAMI SP10 standard.

Comparison to Predicate

The Clever TD-3250 was compared against a mercury sphygmomanometer and a total of 270 measurements. The results generated demonstrated a mean difference of: systole = 1.78 mmHg, SD = 5.65 mmHg, diastole = 1.2 mmHg, SD = 5.21, this meets the ± 5 mmHg and ± 8 mmHg SD allowable under the ANSI/AAMI SP10.

Software

The sponsor provided a detailed software program-related documentation including: level of concern, software description, software requirements specification, design specification and information concerning development. The software report was prepared in accordance with the FDA guidance document "Guide for the Content of Premarket Submission for Software Contained in Medical Devices."

Biocompatibility

The patient contacting material in this device is medical grade coated polyester fabric. This material has been used in four previously cleared submissions k020897, k021225, k012310 and k012796.

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.