

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

A. 510(k) Number:

k062800

B. Purpose for Submission:

Previously cleared devices that have a change in strip (volume, strip application port, read time) and addition of AST sites for the glucose testing portion.

C. Measurand:

Glucose and Blood Pressure

D. Type of Test:

Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

Blood Pressure – Non-invasive Oscillometric

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

Clever Chek TD-3213, Clever Chek TD-3215, Dr. T TD-3216, Clever Chek TD-3217, and Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring Systems

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 (Glucose Test System)

Class II (Blood Pressure Measurement System)

3. Product code:

NBW, CGA, DXN

4. Panel:

75, Clinical Chemistry – Glucose Test System

74, Cardiovascular – Blood Pressure Measurement System

H. Intended Use:

1. Intended use(s):

See Indications for use.

2. Indication(s) for use:

The Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/ Clever Chek TD-3217/ Clever Chek TD-3250 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 from 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, and is not intended for use on neonates.

The alternative site testing in the systems can be used only during steady-state blood glucose conditions.

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.

For the Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/ Clever Chek TD-3217 system, the blood pressure is measured by using a technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 5.25”~7.75”.

For Clever Chek TD-3250 system, 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”.

3. Special conditions for use statement(s):

The alternative site testing in the Clever Chek TD-3213, Clever Chek TD-3215, Dr. T TD-3216, Clever Chek TD-3217, and Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring Systems can be used only during steady-state blood glucose conditions.

4. Special instrument requirements:

Clever Chek TD-3213, Clever Chek TD-3215, Dr. T TD-3216, Clever Chek TD-3217, and Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring Systems

I. Device Description:

The Clever Chek TD-3213, Clever Chek TD-3215, Dr. T TD-3216, Clever Chek TD-3217, and Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring Systems each consist of four main products: the blood glucose meter, test strips (including the “check & code” strip), control solutions (2 levels of TaiDoc control solution – cleared under k012430), and the lancet device (cleared under k833344). These products have been designed and tested to work together as a system to produce accurate blood glucose test results. The systems also have a blood pressure component, though as the changes to the device compared to the predicate involve only the glucose testing portion the focus of the testing was primarily on the blood glucose performance characteristics.

J. Substantial Equivalence Information:

- 1. Predicate device name(s):
ACHTUNG Blood Glucose Monitoring System, Clever Chek TD-3213 and Clever Chek TD-3250 Blood Glucose and Blood Pressure Measurement Systems
- 2. Predicate 510(k) number(s):
k061181, k042795, k061073
- 3. Comparison with predicate:

Similarities		
Item	Devices	Predicate (k061181)
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Test Range	20 – 600 mg/dL	20 – 600 mg/dL
Hematocrit	20-60%	20-60%
Open Use Time (strip)	90 days	90 days
Coding	Code strip	Code strip

Differences		
Item	Devices	Predicate (k061181)
Blood Pressure Cuff	Present	Not Present

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

CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices
CLSI EP9-A: Method Comparison and Bias Estimation Using Patient Samples
ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
ANSI/AAMI SP10: Manual, electronic or automated sphygmomanometers.

L. Test Principle:

For the blood glucose portion: Once a whole blood sample is applied to the sample chamber of the test strip, glucose measurement commences. 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:
The sponsor has evaluated the precision of the device using the TD-3217 meter (which is technologically similar to the TD-3213, TD-3215, TD-3216, TD-3250, and TD-4207 meters). The sponsor evaluated the precision of the TD-3217 using replicate measurements of glucose control solutions and spiked anticoagulated venous

whole blood. Day to day precision testing was performed with 3 levels of TaiDoc control solutions each with 3 different lots test strips. Samples were tested with 10 measurements obtained from 10 meters with each level of control solution (for a total of 300 tests) over 10 days. The range for each control solution level is an experienced result in periods of 6 months. Each level was established as an average value first, which for low is 77 mg/dL, for normal is 135 mg/dL, and for high is 325 mg/dL. Then the range of each level was established from the average minus/plus 20% (20% is from ISO15197, minimum acceptable accuracy), giving low ranges of 61 to 93 mg/dL, normal ranges from 108 to 162 mg/dL, and high ranges from 260 to 390 mg/dL. Results are summarized below.

	Low Control Level (61-93 mg/dL)			Mid Control Level (108-162 mg/dL)			High Control Level (260-390 mg/mL)		
Strip Lot	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)
Mean	78.2	78.8	80.1	133.1	137.5	138.4	324.2	326.0	326.2
SD	1.99	1.63	1.78	4.15	4.01	3.95	7.89	8.36	6.65
CV	2.55%	2.07%	2.22%	3.12%	2.92%	2.86%	2.43%	2.57%	2.04%

Within day precision testing was performed with 5 levels of spiked whole blood (with a hematocrit of ~46%) each with 3 different lots test strips. Samples were tested with 10 measurements obtained from 10 meters with each level of control solution (for a total of 500 tests) over 10 days. Results are summarized below.

	Level 1 (30-50 mg/dL)			Level 2 (51-110 mg/dL)			Level 3 (111-150 mg/mL)		
Strip Lot	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)
Mean	41.9	41.7	41.4	91.0	90.8	91.4	143.2	142.8	143.1
SD	2.02	2.04	2.06	2.66	2.79	2.79	3.21	3.88	3.57
CV	4.83%	4.88%	4.98%	2.92%	3.07%	3.07%	2.24%	2.72%	2.50%

	Level 4 (151-250 mg/dL)			Level 5 (251-400 mg/dL)		
Solution Lot	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)	Lot 1 (meters 1-3)	Lot 2 (meters 4-6)	Lot 3 (meters 7-10)
Mean	240.9	236.9	240.6	363.8	364.6	365.3
SD	6.12	5.82	7.15	6.14	7.28	6.20
CV	2.54%	2.46%	2.97%	1.69%	2.00%	1.70%

To ensure that the meters perform similarly (as they utilize the same fundamental technology), TD-3213, TD-3215, TD-3216, TD-3217, TD-3250, and TD-4207 meters had each meters within day precision were compared using 1 sample at each control solution level for each of the six meters. The TD-4207 is a previously cleared meter (k042005) that does not contain the blood pressure system and uses the old strip type.

It has been included to support the substantial equivalence of the newer meters. Results are summarized below.

Low Control Level (61-93 mg/dL)						
Meter	TD-4207	TD-3213	TD-3215	TD-3216	TD-3250	TD-3217
Mean	79.76	78.24	78.76	78.12	81.16	78.84
SD	1.76	1.48	2.33	1.64	2.25	1.49
CV	2.21%	1.89%	2.96%	2.10%	2.77%	1.89%

Mid Control Level (108-162 mg/dL)						
Meter	TD-4207	TD-3213	TD-3215	TD-3216	TD-3250	TD-3217
Mean	136.4	133.2	136.84	138.76	138.96	137.76
SD	5.24	3.86	4.87	3.48	4.81	3.22
CV	3.84%	2.90%	3.56%	2.51%	3.46%	2.34%

High Control Level (260-390 mg/mL)						
Meter	TD-4207	TD-3213	TD-3215	TD-3216	TD-3250	TD-3217
Mean	326.64	323.20	323.32	320.60	334.16	332.36
SD	12.24	6.49	7.92	9.53	8.58	9.00
CV	3.75%	2.01%	2.45%	2.97%	2.57%	2.71%

b. Linearity/assay reportable range:

The linearity of the device was demonstrated by comparing 9 levels of whole blood samples on the TD-3217 and a glucose reference method (YSI-2300) in k061181. The samples ranged in concentration from a low of approximately 22 mg/dL to a high of approximately 587 mg/dL (from YSI). Linear regression of the comparison data yielded the following relationship: $ACHTUNG = (0.9851 \times YSI-2300) + 5.4$, $r^2 = 0.9995$. The reportable range of the ACHTUNG TD-3217 Blood Glucose Monitoring System 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. The sponsor has shown traceability of the meter to a laboratory analyzer.

d. Detection limit:

20 mg/dL. The sponsor supported this level with a linearity study (above).

e. Analytical specificity:

The specificity of the device was assessed with the TD-3217 meter. Elevated blood triglycerides and the following substances do not affect results: acetaminophen, dopa, methyl dopa, L-dopa and tolbutamide occurring in expected blood concentrations. Reducing substances such as uric acid and ascorbic acid occurring in expected blood concentrations was shown to not cause interference. The altitude study also showed that the percentage of mean difference between strips is within the acceptable range (from ISO15197, minimum acceptance accuracy: within $\pm 20\%$

when glucose concentration $\geq 75\text{mg/dL}$) indicating that the new test strips are equivalent to the predicate strips at the same altitude (up to 10,744 feet). A hematocrit was also performed and the results supported a use of the meter from 20 to 60% hematocrit.

- f. *Assay cut-off:*
Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor demonstrated that the TD-3217 for finger stick is equivalent to a standard method (YSI-2300) and can be used on alternate sites (specifically the capillary blood from finger compared to the palm, forearm, upper arm, calf, and thigh). The sponsor assessed accuracy by having 147 patients from 3 different sites using a standard method compared to finger stick. For the finger stick against the standard method, samples ranged as follows: 10% of samples were 20-50 mg/dL, 36% of samples were 51-110 mg/dL, 29% of samples were 111-150 mg/dL, 11% of samples were 151-250 mg/dL, 15% of samples were 251-600 mg/dL, and 15% of samples were 401-600 mg/dL. For the AST sites, the samples ranged as follows: 40% of samples were 51-110 mg/dL, 30% of samples were 111-150 mg/dL, 20% of samples were 151-250 mg/dL, and 10% of samples were 251-600 mg/dL. All patients blood glucose levels were in a steady state for these studies. The studies are summarized below.

Comparison	N	Slope and y-intercept	r^2
TD-3217 vs. YSI-2300	147	$y = 0.994x + 3.38$	0.984

Difference distribution for glucose concentration $< 75\text{mg/dL}$

Difference within $\pm 5\text{mg/dL}$	Difference within $\pm 10\text{mg/dL}$	Difference within $\pm 15\text{mg/dL}$
11/30 (37%)	25/30 (83%)	29/30 (97%)

97% of the individual difference is within $\pm 15\text{mg/dL}$ when glucose concentration is $< 75\text{mg/dL}$.

Difference distribution for glucose concentration $\geq 75\text{mg/dL}$

Difference within $\pm 5\%$	Difference within $\pm 10\%$	Difference within $\pm 15\%$	Difference within $\pm 20\%$
52/117 (44%)	94/117 (83%)	110/117 (94%)	113/117 (97%)

97% of the individual difference is within $\pm 20\%$ when glucose concentration is $\geq 75\text{mg/dL}$.

	YSI vs. Finger	Finger vs. Palm	Finger vs. Forearm	Finger vs. Upper arm	Finger vs. Calf	Finger vs. Thigh
N	147	121	119	115	117	113

Slope	0.994	0.991	0.948	0.945	1.01	0.931
Intercept	3.38	-0.091	5.92	3.21	-2.63	4.89
r ²	0.984	0.971	0.951	0.951	0.951	0.945

Finger versus YSI and each site met the ISO 15197 requirement of ninety-five percent (95 %) of the individual glucose results falling within ± 15 mg/dL of the results of the manufacturer's measurement procedure at glucose concentrations for samples < 75 mg/dL and within ± 20 % at glucose concentrations ≥ 75 mg/dL. These results are summarized in the table below.

Site	Finger	Palm	Forearm	Upper arm	Calf	Thigh
N	147	121	119	115	1117	113
Percentage That Met ISO Requirement	97% (142/147)	97% (117/121)	95% (113/119)	96% (110/115)	96% (112/117)	96% (108/113)

The sponsor also has in the labeling for each meter instructions at what intervals AST can be used and when AST should not be used.

To ensure that the meters perform similarly (as they utilize the same fundamental technology), TD-3213, TD-3215, TD-3216, TD-3217, TD-3250, and TD-4207 meters were compared against a standard laboratory method (YSI-2300). This accuracy test was performed using fresh capillary whole blood samples with a range of 28-571 mg/dL. Results are summarized below.

Comparison	N	Slope and y-intercept	r
TD-3213 vs. YSI-2300	135	$y = 0.972x + 4.81$	0.990
TD-3215 vs. YSI-2300	135	$y = 0.993x + 3.43$	0.990
TD-3216 vs. YSI-2300	135	$y = 0.974x + 4.51$	0.988
TD-3250 vs. YSI-2300	135	$y = 0.979x + 6.01$	0.989
TD-3217 vs. YSI-2300	135	$y = 0.968x + 6.56$	0.988
TD-4207 vs. YSI-2300	135	$y = 0.978x + 4.69$	0.986

Difference distribution for glucose concentration < 75 mg/dL

	Difference within ± 5 mg/dL	Difference within ± 10 mg/dL	Difference within ± 15 mg/dL
TD-3213	11/25 (44%)	18/25 (72%)	24/25 (96%)
TD-3215	10/25 (40%)	20/25 (80%)	25/25 (100%)
TD-3216	10/25 (40%)	19/25 (76%)	24/25 (96%)
TD-3250	12/25 (48%)	17/25 (68%)	25/25 (100%)
TD-3217	9/25 (36%)	14/25 (56%)	24/25 (96%)
TD-4207	12/25 (48%)	20/25 (80%)	24/25 (96%)

96-100% of the individual difference is within ± 15 mg/dL when glucose concentration is < 75 mg/dL.

Difference distribution for glucose concentration ≥ 75 mg/dL

	Difference within ± 5 %	Difference within ± 10 %	Difference within ± 15 %	Difference within ± 20 %
TD-3213	54/110 (49%)	88/110 (80%)	100/110 (91%)	106/110 (96%)
TD-3215	53/110 (48%)	81/110 (74%)	97/110 (88%)	106/110 (96%)
TD-3216	50/110 (45%)	81/110 (74%)	93/110 (85%)	106/110 (96%)
TD-3250	55/110 (50%)	83/110 (75%)	98/110 (89%)	105/110 (95%)
TD-3217	48/110 (44%)	76/110 (69%)	96/110 (87%)	106/110 (96%)
TD-4207	56/110 (51%)	84/110 (76%)	102/110 (93%)	105/110 (95%)

95-96% of the individual difference is within ± 20 % when glucose concentration is ≥ 75 mg/dL.

Each meter met the ISO 15197 requirement of ninety-five percent (95 %) of the individual glucose results falling within ± 15 mg/dL of the results of the manufacturer's measurement procedure at glucose concentrations for samples < 75 mg/dL and within ± 20 % at glucose concentrations ≥ 75 mg/dL.

b. *Matrix comparison:*

See above: *Method comparison with predicate device*

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 included the following Expected Values for normal glucose levels in their strip labeling:

Status	Range (mg/dL)	Range (mmol/L)
Before breakfast	70-105	3.9-5.8
Before lunch or dinner	70-110	3.9-6.1
1 hour after meals	< 160	< 8.9
2 hours after meals	< 120	< 6.7
Between 2 and 4 AM	> 70	> 3.9

Source: Krall, L.P. and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 138.

N. Instrument Name:

Clever Chek TD-3213, Clever Chek TD-3215, Dr. T TD-3216, Clever Chek TD-3217, and Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring Systems

O. System Descriptions:

1. Modes of Operation:
Each test strip is single use and must be replaced with a new strip for additional readings.
2. Software:
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
Yes 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, the palm, the forearm, the upper-arm, the calf, and the thigh 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 provided with each batch of test strips to calibrate the meter for that batch. No further calibrations are required of the user.
6. Quality Control:
The sponsor is providing a high and low glucose control solution with this device. When a test strip is inserted into the meter, the control mode can be activated. This prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the troubleshooting section of the owner's manual if control results fall outside these ranges.

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

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.