

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

A. 510(k) Number:

k062235

B. Purpose for Submission:

Change in volume, strip application port, read time, and addition of AST sites.

C. Measurand:

Glucose

D. Type of Test:

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

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 Blood Glucose Monitoring Systems

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Glucose Test System
2. Classification:
Class II
3. Product code:
NBW, CGA
4. Panel:
75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
See Indications for use.
2. Indication(s) for use:
The Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 Blood Glucose Monitoring Systems 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.
3. Special conditions for use statement(s):
The alternative site testing in the the Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 Blood Glucose Monitoring Systems can be used only during steady-state blood glucose conditions.

4. Special instrument requirements:

Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 Blood Glucose Monitoring Systems

I. Device Description:

The Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 Blood Glucose 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 sponsor recommends that only TaiDoc test strips and control solutions be used with the blood glucose meters. The performance of the test strips is verified by the control solutions. The check & code strip verifies the status of the meter. The meters were originally cleared under 510(k)s k042005 (Easy Check TD-4209, Clever Chek TD-4222) and k051854 (Clever Chek TD-4225 and Clever Chek TD-4226) and were themselves modifications of k041107. Model TD-4207 was cleared originally under 510(k) k042005, and then cleared for use with new strips and alternate testing under 510(k) k061181 with the trade name ACHTUNG.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACHTUNG TD-4207, Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 Blood Glucose Monitoring Systems

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

k042005, k061181

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
Temperature Range	50-104°F, 10-40°C	50-104°F, 10-40°C
Humidity Range	Below 85%	Below 85%
Warranty (meter)	5 years	5 years
Open Use Time (strip)	90 days	90 days
Coding	Code strip	Code strip
Memory Capability	450 measurements	450 measurements
Power	CR2032 3V lithium battery	CR2032 3V lithium battery

Differences		
Item	Devices	Predicate (k061181)
Mechanical Appearance	Varies depending on model	Rounded form

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

NCCLS 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. The results presented in this submission support that the devices conform to acceptance criteria in this ISO 15197.

L. Test Principle:

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):

Since the ACHTUNG meter has the same technological characteristics (with the exception of mechanical appearance) as the Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 Blood Glucose Monitoring Systems, the ACHTUNG performance data was used to help support the addition of the test strips cleared in k061181 and the addition of a claim for alternate site testing in this submission. The sponsor also supplied performance data that supports that the Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 Blood Glucose Monitoring Systems perform similarly to the predicate device (and to each other).

1. Analytical performance:

a. *Precision/Reproducibility:*

The sponsor evaluated the precision of the ACHTUNG meter (which is technologically similar to the Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 meters) and the modified strips in k061181. The sponsor evaluated replicate measurements of glucose control solutions and anticoagulated venous whole blood. In order to determine that the change in sample volume does not affect precision, the sponsor tested four volume levels (0.5, 0.6, 0.7, and 0.8 μ L) of venous whole blood collected from 10 volunteers in k061181. The ten samples were pooled together, depleted of glucose, and then separated into three groups. Each group was spiked with a dextrose solution to within the desired concentration range: low 60-92 mg/dL, normal 109-165 mg/dL and high 259-389 mg/dL. Different testing volumes (0.5uL, 0.6uL, 0.7uL and 0.8 uL) of each sample were evaluated for repeatability. Since the volume claimed is 0.7 μ L, only the 0.7 μ L data from k061181 is presented below.

Patient	Low Control Level (60-92 mg/dL)			Mid Control Level (109-165 mg/dL)			High Control Level (259-389 mg/mL)		
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
1	68	68	72	139	139	144	309	309	300
2	68	68	65	132	132	141	310	310	297
3	70	70	71	130	130	133	314	314	307
4	68	68	71	136	136	137	308	308	300
5	72	72	70	133	133	141	311	311	297
6	72	72	72	133	133	134	312	312	313
7	70	70	74	137	137	131	306	306	305
8	69	69	71	135	135	134	313	313	302
9	65	65	69	134	134	141	310	310	301
10	64	64	74	137	137	145	305	305	305
Total CV(%)	3.98			2.85			1.60		

To ensure that the meters perform similarly to the predicate device (and to each other), the strip cleared in k061181 was tested with the Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 meters. Precision testing was performed with 3 levels of TaiDoc control solutions with a single lot of strips with 25 measurements obtained for each meter at each control level. The average level for each control solution level is based on the observed result over a 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 solution				
meter	TD-4207	TD-4209	TD-4222	TD-4225
Mean	78.48	78.24	75.44	75.64
SD	2.16	1.48	1.92	1.82
CV(%)	2.76	1.89	2.54	2.41

Normal control solution				
meter	TD-4207	TD-4209	TD-4222	TD-4225
Mean	136.16	133.20	134.12	133.36
SD	3.98	3.86	4.78	4.28
CV(%)	2.92	2.90	3.56	3.21

High control solution				
meter	TD-4207	TD-4209	TD-4222	TD-4225
Mean	326.96	323.20	328.12	327.96
SD	7.61	6.49	9.20	7.24
CV(%)	2.33	2.01	2.80	2.21

b. Linearity/assay reportable range:

The linearity of the device was demonstrated by comparing 120 prepared whole blood samples on the ACHTUNG TD-4207 Blood Glucose Monitoring System and a glucose reference method (YSI-2300) in k061181. The samples ranged in concentration from a low of approximately 23 mg/dL to a high of approximately 605 mg/dL (from YSI). Linear regression of the comparison data yielded the following relationship: $ACHTUNG = (1.0052 \times YSI-2300) + 1.7264$, $r = 0.9896$. The reportable range of the ACHTUNG TD-4207 Blood Glucose Monitoring System 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 in k041107. Given that the technology has not changed from k041107, the sponsor claims that elevated blood triglycerides and the following substances do not affect results: acetaminophen, dopa, methyl dopa, L-dopa and tolbutamide occurring in expected blood concentrations. Due to the change in read time of the glucose oxidase reaction, the sponsor provided reducing substances studies along with an altitude study for the new strips. Reducing substances such as uric acid and ascorbic acid occurring in expected blood concentrations (0-3 mg/dL and 5-20 mg/dL respectively) was shown to be equivalent

to the predicate strip. 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 ≥ 75 mg/dL) indicating that the new test strips are equivalent to the predicate strips at the same altitude (up to 10,744 feet).

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

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor demonstrated in k061181 that the ACHTUNG TD-4207 Blood Glucose Monitoring System (as they share the same fundamental technology as the Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 meters) 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 in k061181 by having 120 patients for the standard method compared to finger stick and 100 patients for each alternative anatomical testing site test the meter. For the finger stick against the standard method, samples ranged as follows: 10% of samples were 20-50 mg/dL, 35% of samples were 51-110 mg/dL, 30% of samples were 111-150 mg/dL, 10% of samples were 151-250 mg/dL, 10% of samples were 251-400 mg/dL, and 5% 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 251-400 mg/dL. All patients blood glucose levels were in a steady state for these studies. The studies from k061181 are summarized below:

	YSI vs. Finger	Finger vs. Palm	Finger vs. Forearm	Finger vs. Upper arm	Finger vs. Calf	Finger vs. Thigh
N	120	100	100	100	100	100
Slope	1.0052	1.0057	0.8716	0.9102	0.9173	0.9842
Intercept	1.7264	1.8744	9.1884	6.2178	5.3413	0.7822
r	0.9948	0.9889	0.9839	0.9822	0.9822	0.9805

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 $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL. These results from k061181 are summarized in the table below.

Site	Finger	Palm	Forearm	Upper arm	Calf	Thigh
N	120	100	100	100	100	100
Percentage That Met ISO Requirement	100% (120/120)	99% (99/100)	100% (100/100)	98% (98/100)	98% (98/100)	98% (98/100)

The sponsor includes in the labeling for each meter instructions concerning conditions under which AST can and cannot be used.

To ensure that the meters perform similarly to the predicate device, the Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 meters were compared against a standard laboratory method (YSI-2300). This accuracy test was performed using fresh capillary whole blood samples from the finger with a range of 28-571 mg/dL. Results are summarized below.

Comparison	N	Slope and y-intercept	r
TD-4207 vs. YSI-2300	120	$y=0.999x+2.853$	0.989
TD-4209 vs. YSI-2300	120	$y=0.997x+3.771$	0.990
TD-4222 vs. YSI-2300	120	$y=0.995x-1.857$	0.982
TD-4225 vs. YSI-2300	120	$y=1.005x-2.820$	0.984

Difference distribution for glucose concentration <75mg/dL

	Difference within $\pm 5\text{mg/dL}$	Difference within $\pm 10\text{mg/dL}$	Difference within $\pm 15\text{mg/dL}$
TD-4207	12/21(57%)	20/21(95%)	21/21(100%)
TD-4209	13/21(62%)	21/21(100%)	21/21(100%)
TD-4222	13/21(62%)	18/21(86%)	21/21(100%)
TD-4225	10/21(48%)	15/21(71%)	21/21(100%)

100% of the individual difference is within $\pm 15\text{mg/dL}$ when glucose concentration is <75mg/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 $\pm 20\%$
TD-4207	41/99(41%)	77/99(78%)	92/99(93%)	97/99(98%)
TD-4209	47/99(47%)	74/99(75%)	91/99(92%)	95/99(96%)
TD-4222	45/99(45%)	67/99(68%)	93/99(94%)	95/99(96%)
TD-4225	43/99(43%)	71/99(71%)	89/99(90%)	95/99(96%)

96% of the individual difference is within $\pm 20\%$ when glucose concentration is $\geq 75\text{mg/dL}$.

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

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 meals	70-110	3.9-6.1
2 hours after meals	<120	<6.7

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

N. Instrument Name:

Easy Check TD-4209, Clever Chek TD-4222, Clever Chek TD-4225 and Clever Chek TD-4226 Blood Glucose 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 reviewed applicant's Hazard Analysis and software development processes for this line of product types in k041107. See k041107 for more information.
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.