

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

A. 510(k) Number:

k073119

B. Purpose for Submission:

Modification to previously cleared device for the use of one calibration code for all test strip lots and the addition of up and down buttons to the meter for scrolling to desired parameters and a repeat button to replay the previous voice instruction. Test strips and control solutions unchanged from predicate device.

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative (glucose oxidase)

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

Clever Chek TD-4232 Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345 Glucose Test System

2. Classification:

Class II

3. Product code:

NBW – System, Test, Blood Glucose, Over the Counter

CGA – Glucose Oxidase, Glucose

4. Panel:

75, Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See Indications for Use below

2. Indication(s) for use:

The Clever Chek TD-4232 Blood Glucose 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 contains a speaking functionality which provides step by step instructions to aid visually impaired persons.

3. Special conditions for use statement(s):

For over the counter use.

Not intended for the diagnosis of or screening for diabetes and not intended for use on neonates. The device should not be used for patients who are dehydrated, in shock, critically ill or in a hyperosmolar state.

4. Special instrument requirements:

Clever Chek TD-4232 Blood Glucose Meter

I. Device Description:

The Clever Chek Blood Glucose Monitoring System consists of a glucose meter, blood glucose test strips, two levels of control solutions, a lancing device, lancets, and instructions for use.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Clever Chek TD-4223 Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k063212
3. Comparison with predicate:

Similarities		
Item	Subject Device	Predicate
Detection method	Amperometry	Amperometry
Enzyme	Glucose oxidase	Glucose oxidase
Sample volume	0.7 uL	0.7 uL
Reaction time	7 seconds	7 seconds
Measurement range	20-600 mg/dL	20-600 mg/dL
Speaker function	yes	yes

Differences		
Item	Device	Predicate
Calibration	One code for all strip lots	Code strip required
Button configuration	Up and down buttons to go to desired parameter; repeat button to replay previous voice instruction	Main button to scroll through parameters; no ability to replay previous voice instruction

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

ISO 15197, In vitro diagnostic test systems –Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

CLSI EP9-A, Method comparison and bias estimation using patient samples

ISO 14971, Medical devices, Application of risk management to medical devices

L. Test Principle:

To perform a test, the test strip is inserted into the monitor. A drop of blood is applied to the end of the strip and automatically drawn into the sample chamber. Glucose measurement is based on electrical current caused by the reaction of glucose in the sample with the reagents contained on the strip. The current resulting from this enzymatic reaction is proportional to the glucose concentration in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Established in predicate submission (k063212)

b. Linearity/assay reportable range:

Established in predicate submission (k063212)

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

The Clever Chek TD-4232 does not require the use of a code strip to code the meter for different strip lots. The sponsor has established acceptance criteria which include accuracy and imprecision to ensure that the test strip performance can support use of a single calibration code at the time of manufacturing. A risk analysis that addresses issues related to the single calibration code was provided by the sponsor. The user verifies that the correct code appears on the meter screen and is printed on the test strip vial label before measurement.

d. Detection limit:

Established in predicate submission (k063212)

e. Analytical specificity:

Established in predicate submission (k063212)

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted a study to demonstrate equivalence between the proposed device and the predicate. A total of 118 capillary whole blood samples, ranging from 22 to 589 mg/dL were tested on the subject and predicate devices, as well as the YSI. Samples less than 40 mg/dL and greater than 400 mg/dL were prepared from a pooled capillary whole blood specimen and spiked to the desired levels. The linear regressions were as follows:

subject device (TD-4232) vs. YSI $y = 0.978x + 3.579, r = 0.993$

predicate device (TD-4223) vs. YSI $y = 0.996x + 2.139, r = 0.994$

b. Matrix comparison:

Alternative sampling site performance from the palm, forearm, upper-arm, calf and thigh established in predicate submission (k063212).

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):

To verify that the new button configuration did not affect performance in visually-impaired users, the sponsor conducted a user study to demonstrate device performance in the hands of visually impaired users. A total of 113 subjects performed fingersticks and tested themselves, using only the audible and written instructions provided by and with the device. Immediately following this testing, a second fingerstick was performed on the same subjects by trained healthcare professionals. The linear regression comparing lay user to professional results from this analysis is as follows:

$Y = 0.9881x + 0.6231, r = 0.984$, sample range = 41 – 461 mg/dL

Two categories for visual impairment are defined in The World Health Organization International Classification of Diseases, 9th Revision, as low vision, with visual acuity of <0.3 and ≥ 0.05 , and blindness, with visual acuity < 0.05 including no light perception. The sample distribution for the user study was a total distribution of 76% (or 86 out of 113) with low vision and 24% (or 27 out of 113) with blindness.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected blood glucose levels for people without diabetes (referenced from ADA Clinical Practice Recommendations, 2003):

Fasting and before meals < 110 mg/dL

2 hours after meals < 140 mg/dL

N. Instrument Name:

Clever Chek TD-4232 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

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, palm, forearm, upper-arm, calf and thigh. Since the whole blood sample is applied directly to the test strip, there are no special handling or storage issues.

5. Calibration:

One calibration code is used for all lots of test strips. The user verifies that the correct code appears on the meter screen and is printed on the test strip vial label before measurement.

6. Quality Control:

Glucose control solutions at two concentrations are provided by the sponsor and should be run with this device. An acceptable range for each control is printed on the test strip vial. The user is instructed to contact the Customer Help line if control results fall outside these ranges.

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

Not applicable.

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.