

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

A. 510(k) Number:

k072784

B. Purpose for Submission:

Previously cleared product with modification for the addition of a speaker function and the use of one calibration code for all test strips lots

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, glucose oxidase

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

Prodigy Autocode Blood Glucose Monitoring System

Clever Chek TD-4227 Blood Glucose Monitoring System

G. Regulatory Information:

| Product Code | Classification | Regulation Section | Panel |
|--------------|----------------|--------------------|---------------|
| NBW and CGA | Class II | 862.1345 | 75, Chemistry |

H. Intended Use:

1. Intended use(s):

See indication for use below.

2. Indication(s) for use:

The Prodigy Autocode/Clever Chek TD-4227 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 also includes a speaking functionality to aid visually impaired persons. It is not intended for the diagnosis of or screening for diabetes mellitus.

The alternative site testing in the Prodigy Autocode/Clever Chek TD-4227 Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

3. Special conditions for use statement(s):

It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. For in vitro diagnostic use only, Over the Counter and professional use. The device should not be used for patients who are dehydrated, in shock, critically ill and in a hyperosmolar state.

4. Special instrument requirements:

Prodigy Autocode and Clever Chek TD-4227 Blood Glucose Monitoring Systems

I. Device Description:

The Prodigy Autocode and clever Chek TD-4227 Blood Glucose Monitoring Systems consists of the glucose meter, blood glucose test strips, lancet device, two levels of control solutions and instructions for use. These meters also come with a speaker function to help visually impaired individuals perform a test. The meters were previously cleared under k062235.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Clever Chek TD-4222 Blood Glucose Monitoring System, TaiDoc Technology Corp.

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

k062235

3. Comparison with predicate:

| Similarities | | |
|---------------------|-----------------|------------------|
| Item | Device | Predicate |
| Detection Method | Amperometry | Amperometry |
| Enzyme | Glucose oxidase | Glucose oxidase |
| Sample volume | 0.7 uL | 0.7 uL |
| Measurement range | 20-600 mg/dL | 20-600 mg/dL |
| Reaction time | 7 seconds | 7 seconds |

| Differences | | |
|--------------------|---|--|
| Item | Device | Predicate |
| Autocode | No code strip is not required by the user prior to testing blood sample | User inserts the code strip into the meter prior to testing blood sample |
| Size | 79(L) x 48 (W) x 17 (H) | 96 (L) x 45 (W) x 23 (H) |
| Speaker function | Yes | No |

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

None were referenced.

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 with the reagents contained on the strip's electrodes. 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 the original submission (k062235)

b. Linearity/assay reportable range:

Established in the original submission (k062235)

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

The Prodigy Autocode and Clever Chek TD-4227 are no user entered code meters

having the single calibration code programmed into the meters at the time of manufacturing. 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.

d. Detection limit:

Established in the original submission (k062235)

e. Analytical specificity:

Established in the original submission (k062235)

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A consumer study was performed with a total of 102 visually impaired lay-users. Visually impaired participants are defined in the ICD-9 of World Health Organization as the following; Low vision <0.3 and ≥ 0.05 and Blindness <0.05 including NLP (no light perception). The lay-users ranged in age, education and equally divided between males and females. 73% of the participants were defined as having low vision while 27% were defined as having blindness. Each participant performed a finger stick and tested their blood following instructions given by the speaker function of the meter. A trained professional then performed a finger stick test, testing the blood on a reference method (YSI).

| | Number of Samples | Linear Regression | r value | Sample Range (mg/dL) | % Error Grid | |
|---------------------------------------|-------------------|-----------------------|---------|----------------------|--------------|----|
| | | | | | A | B |
| Lay-user vs Professional finger stick | 102 | $y = 1.028x - 7.4761$ | 0.965 | 43-441 | 95% | 5% |

b. Matrix comparison:

Not applicable

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):*

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 | 70-100 (mg/dL) (3.9-6.1 mmol/L) |
| 2 hours after meals | Less than 140 mg/dl (7.8 mmol/L) |

Source: ADA Clinical Practice Recommendations 2003

N. Instrument Name:

Prodigy Autocode Blood Glucose Monitoring System and Clever Chek TD-4227 Blood Glucose Monitoring System

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 fingertip, 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:

Rather than the user inputting a new calibration code for each lot of strips, the calibration is factory set by the manufacturer..

6. Quality Control:

The sponsor provides one level of either the Prodigy Control Solution or TaiDoc Control Solution. The other two levels of control may be purchased separately. To perform a control test the user is instructed to press the M button after the blood drop has appeared on the display. This prevents control results from being stored in the internal memory. The acceptable range for each level is printed on the test strip vial label. If control results fall outside these ranges, the user is referred to a list of troubleshooting steps and the customer care line.

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.