

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

**A. 510(k) Number:**

k090188

**B. Purpose for Submission:**

New device

**C. Measurand:**

Whole blood glucose

**D. Type of Test:**

Quantitative amperometric assay (glucose oxidase)

**E. Applicant:**

TaiDoc Technology Corporation

**F. Proprietary and Established Names:**

U-RIGHT TD-4227 No Coding 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, CGA

4. Panel:

75 (Clinical Chemistry)

## **H. Intended Use:**

### 1. Intended use(s):

Refer to indications for use below.

### 2. Indication(s) for use:

The U-RIGHT TD-4227 No Coding 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, and is not intended for use on neonates.

The alternative site testing in the U-RIGHT TD-4227 No Coding Blood Glucose Monitoring 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):

This device is not intended for the diagnosis of or screening for diabetes mellitus, and is 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. For in vitro diagnostic use only. This device may be used over the counter and by health care professionals.

### 4. Special instrument requirements:

U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System

## **I. Device Description:**

This glucose meter was previously cleared under k072784 as the TaiDoc Prodigy Autocode Blood Glucose Monitoring System and the TaiDoc Clever Chek TD-4227 Blood Glucose Monitoring System. The predicate for k072784 was k062235, also from TaiDoc, and performance data from k062235 was used to support the clearance of k072784.

The new device in this submission is the same as the one reviewed in k072784 except for the brand name.

## **J. Substantial Equivalence Information:**

1. Predicate device name(s):

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

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

k072784

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Alternate sampling sites	Same	Palm, forearm, upper arm, calf, thigh
Methodology	Same	Quantitative, amperometric, using glucose oxidase
Sample size	Same	0.7 µL
Reaction time	Same	7 seconds
Measuring range	Same	20 – 600 mg/dL
Environmental conditions	Same	10 – 40° C Below 85% relative humidity
Memory capacity	Same	450 measurements with date and time

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Device Name	U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System	Clever Chek TD-4227 Blood Glucose Monitoring System , Prodigy Autocode Blood Glucose Monitoring System

**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:*

Precision and reproducibility were evaluated in k062235.

*b. Linearity/assay reportable range:*

Linearity was evaluated in k062235.

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

The controls supplied with this device were cleared under k072784.

*d. Detection limit:*

The detection limit of the U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System is 20 mg/dL, and was evaluated in k062235.

*e. Analytical specificity:*

Specificity was evaluated in k062235.

*f. Assay cut-off:*

Not applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

Method comparison studies were evaluated in k072784.

*b. Matrix comparison:*

Not applicable – capillary whole blood is the only matrix that has been validated with this 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 includes the following Expected Values for people without diabetes in their glucose strip labeling:

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Status	Range
Fasting and before meals <sup>1</sup>	70-110 (mg/dL) (3.9-6.1 mmol/L)
2 hours after meals <sup>2</sup>	Less than 140 mg/dl (7.8 mmol/L)

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Sources:

<sup>1</sup>Tietz Textbook of Clinical Chemistry, 1999

<sup>2</sup>American Diabetes Association Clinical Practice Recommendations, 2003

**N. Instrument Name:**

U-RIGHT TD-4227 No Coding 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 additional readings.

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 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:

Calibration is factory set by the manufacturer. No coding by the user is required.

6. Quality Control:

The sponsor provides one level of 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.