

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

A. 510(k) Number:

k073118

B. Purpose for Submission:

Previously cleared product with modifications for more alternate sites and for use by visually impaired individuals

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, glucose oxidase

E. Applicant:

Diagnostic Devices Inc.

F. Proprietary and Established Names:

Prodigy Voice 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 – Blood glucose test system, over the counter
CGA – Glucose oxidase, glucose
4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
See indication(s) for use below.
2. Indication(s) for use:
The Prodigy Voice 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):

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:

Diagnostic Devices Inc., Prodigy Voice Blood Glucose Monitoring System

I. Device Description:

The Prodigy Voice Blood Glucose Monitoring System consists of blood glucose meter, blood glucose test strips, control solutions, the lancing device, and lancets. The meter also comes with a speaker function to help visually impaired individuals perform a test. The meter was previously cleared under k060467 with the measurement function the same, but has a different appearance. The Prodigy Voice Blood Glucose Monitoring System allows more alternate sites (forearm, upper arm, calf and thigh) for blood glucose testing than cleared under k063212 (palm) and its use is by visually impaired individuals.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Prodigy Blood Glucose Test System

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

k060467

3. Comparison with predicate:

Item	Predicate device	Proposed device
k number	k060467	---
Brand name	Prodigy Blood Glucose Test System	Prodigy Voice Blood Glucose Monitoring System
Indications for use	The Prodigy Blood Glucose Test System is intended to be used for the quantitative measurement of glucose in capillary whole blood from the fingertip and palm. It is intended for use by healthcare professionals and people with	The Prodigy Voice 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,

Item	Predicate device	Proposed device
k number	k060467	---
	<p>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 not intended for use on neonates. The Prodigy meter is to be used with the Prodigy Blood Glucose Test Strip and the Prodigy Glucose Control Solutions.</p>	<p>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.</p> <p>The alternative site testing in this system can be used only during steady-state blood glucose conditions.</p> <p>This system contains a speaking functionality which provides step by step instructions to aid visually impaired persons.</p>
Similarities		
Item	Prodigy	Prodigy Voice
Detection method	Amperometry: measuring a current produced by a chemical reaction	Same as predicate
Enzyme	Glucose oxidase	Same as predicate
Temperature compensation	Automatic compensation with built-in thermister	Same as predicate
Sample volume (µL)	0.7 uL	Same as predicate
Reaction time (sec)	7	Same as predicate
Measurement range	20-600 mg/dL	Same as predicate
Operating condition	10°C- 40°C Below 85% R.H.	Same as predicate

Item	Predicate device	Proposed device
k number	k060467	---
Strip vial opened use time	90 days	Same as predicate
Memory feature	450 measurements with day and time	Same as predicate
Day average	7-, 14-, 21-, 28-, 60- and 90-day average glucose result	Same as predicate
Auto Shut Off (min)	3	Same as predicate
Alarm	Beeping sound and/or error message in LCD display	Same as predicate
Communication	RS232 port	Same as predicate
Speaking function	yes	yes
Differences		
Item	Prodigy	Prodigy Voice
Test Strip Calibration	Coding with each lot with a Code strip	One code for all lots, with the user checking that the code number that appears on the meter display and on the test strip vials is correct.
Size (mm)	75mm x 45mm x 16mm	95(L) x 55(W) x 18(H)
Weight (g)	48.5 g	75 g

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

- CLSI - Method Comparison and Bias Estimation Using Patient Samples - EP09-A2
- CLSI - Evaluation of Precision Performance of Clinical Chemistry Devices - EP05-A2
- ISO15197:2003 - In vitro diagnostic test systems — Requirements for blood - glucose monitoring systems for self-testing in managing diabetes mellitus
- ISO14971 – Medical devices – Application of risk management to medical devices.

L. Test Principle:

The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current and displays the

corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

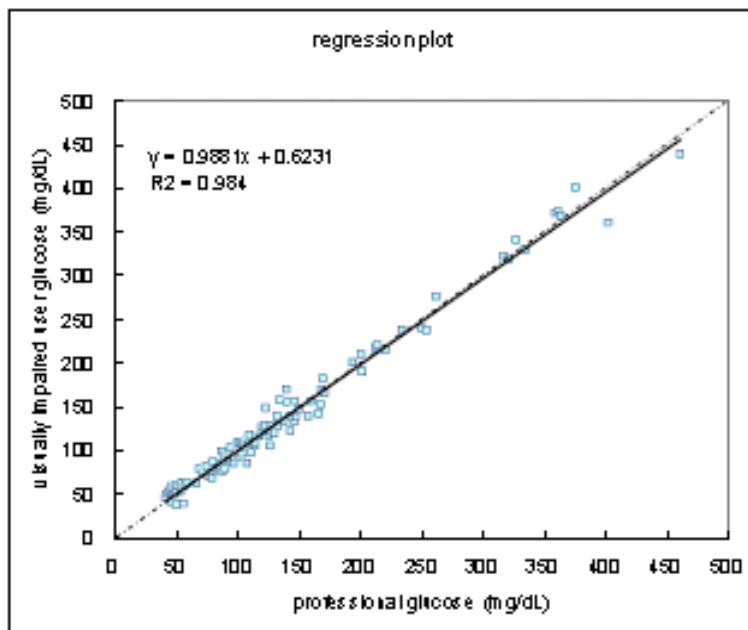
M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Established in the original submission (k060467)
 - b. *Linearity/assay reportable range:*
Established in the original submission (k060467)
 - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Established in the original submission (k060467)
 - d. *Detection limit:*
Established in the original submission (k060467)
 - e. *Analytical specificity:*
Established in the original submission (k060467)
 - f. *Assay cut-off:*
Not Applicable
2. Comparison studies:
 - a. *Method comparison with predicate device:*
The applicant states that the guidelines, ISO 15197 and CLSI - EP9-A were followed in this study to assess visual impaired use.

One hundred and thirteen subjects who are visually impaired patients as defined in ICD-9 of World Health Organization were involved in this study. They were given Prodigy Voice meters that contain speaking function which guide glucose testing step-by-step in English. The lay-users ranged in age, education and were equally divided between males and females. 74% of the participants were defined as having low vision while 26% were defined as having blindness.

Test results were compared to those obtained from trained health professionals performing glucose test on above subjects. The following regression plot was used to assess the clinical significance of error in the blood glucose monitoring results.

$$N=113, \text{ range} = 41\text{-}461 \text{ mg/dL}$$
$$y = 0.9881x + 0.6231, R^2 = 0.984$$



97% (110/113) of the individual difference were within $\pm 15\text{mg/dL}$ when glucose concentrations are less than 75mg/dL and were within $\pm 20\%$ when glucose concentrations are $\bullet 75\text{mg/dL}$, meeting ISO 15197 criteria.

b. *Matrix comparison:*
Not Applicable

3. Clinical studies:

a. *Clinical Sensitivity:*
Not Applicable

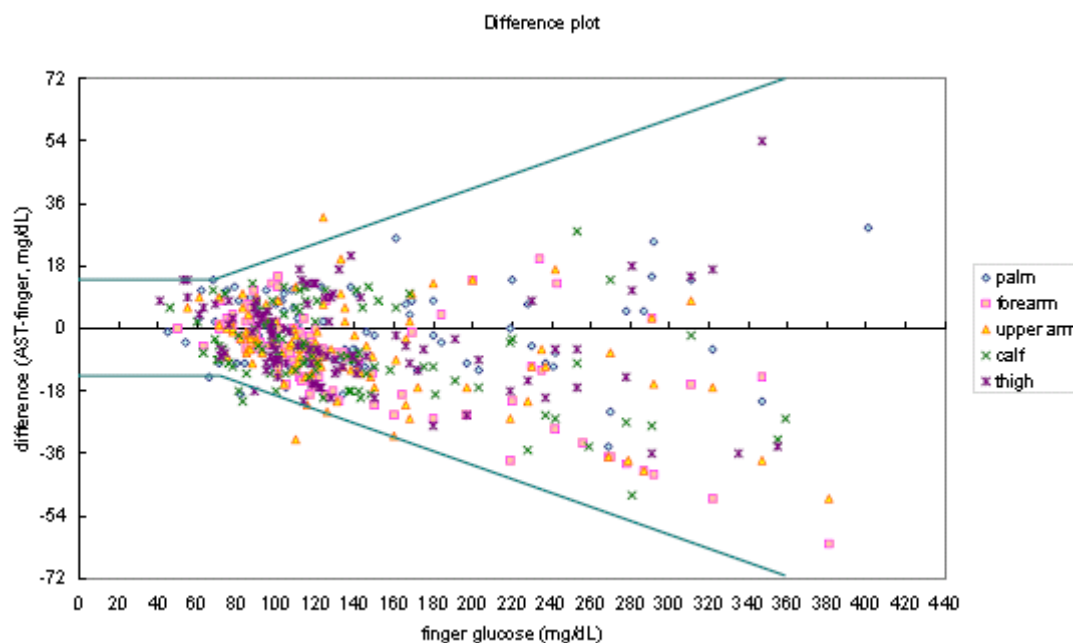
b. *Clinical specificity:*
Not Applicable

c. Other clinical supportive data (when a. and b. are not applicable):

A study using ISO 15197 and CLSI - EP9-A as guidance was conducted to evaluate user error, comfort and ease of use of Prodigy Voice BGM System test strip for blood glucose monitoring using the palm, the forearm, the upper arm, the calf and the thigh as an alternative sampling sites. Participants, who are able to read manual in English, were instructed to read the user manual and perform testing on the finger and AST sites. Testing using samples from alternative sites was immediately followed by finger-stick blood testing by the participants.

The following regression analysis was used to assess the clinical significance of error in the blood glucose monitoring results.

Comparison	N	Range (mg/dL)	Slope and y-intercept	R square
Palm vs. finger	100	45-347	$y = 1.006x - 1.874$	0.978
Forearm vs. finger	100	50-381	$y = 0.872x + 9.188$	0.968
Upper arm vs. finger	100	55-381	$y = 0.910x + 6.218$	0.965
Calf vs. finger	100	46-359	$y = 0.917x + 5.341$	0.965
Thigh vs. finger	100	41-355	$y = 0.984x - 0.782$	0.961



The two bold lines represented the acceptance criteria from ISO 15197: within ± 15 mg/dL when glucose concentration < 75 mg/dL and within $\pm 20\%$ when glucose concentration ≥ 75 mg/dL.

AST site	Percentage of the individual difference is within ± 15 mg/dL when glucose concentration < 75 mg/dL and within $\pm 20\%$ when glucose concentration ≥ 75 mg/dL meeting ISO 15197 criteria
Palm	99% (99/100)
Forearm	100% (100/100)
Upper arm	98% (98/100)
Calf	98% (98/100)
Thigh	98% (98/100)

4. Clinical cut-off:
Not Applicable

5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	Less than 110 mg/dL
2 hours after meals	Less than 140 mg/dL

Source: ADA Clinical Practice Recommendations 2003

Test results below 60 mg/dL¹ mean low blood glucose (hypoglycemia). Test results greater than 240 mg/dL (13.3mmol/L)² mean high blood glucose (hyperglycemia).

- 1: Kahn, R., and Weir, G.: Joslin's Diabetes Mellitus, 13th ed. Philadelphia: Lea and Febiger (1994), 489.
- 2: Krall, L.P., and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 261-263.

N. Instrument Name:

Diagnostic Devices, Prodigy Voice 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 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. Samples are stored in memory and identified by date and time.

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 the Prodigy 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.