

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

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

k122338

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Capillary whole blood glucose

**D. Type of Test:**

Quantitative, Amperometric method, Glucose oxidase

**E. Applicant:**

Prodigy® Diabetes Care LLC

**F. Proprietary and Established Names:**

Prodigy® Preferred Blood Glucose Monitoring System

**G. Regulatory Information:**

<b>Device</b>	<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
Preferred Blood Glucose Monitoring System	NBW, CGA (over the counter)	Class II	21 CFR § 862.1345, glucose test system, over the counter, Glucose oxidase	75-Chemistry

**H. Intended Use:**

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Prodigy Preferred Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy Preferred Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Prodigy Preferred Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Prodigy Preferred Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Prodigy No Coding Test Strips are for use with the Prodigy Preferred Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use.

Inaccurate results may occur in severely hypotensive individuals or patients in shock.

Inaccurate results may occur for individuals experiencing a hyperglycemic-hyperosmolar state.

Severe dehydration and excessive water loss may cause false low results.

Never chew or swallow a test strip.

All parts of this kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

These devices are intended to be used for patient self-monitoring and should not be used to collect blood from more than one person as this poses a risk of transmitting blood-borne pathogens such as Hepatitis B or HIV.

Prodigy Preferred Meter should not be used for calibrating CGMs or for insulin dosing calculations.

Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

4. Special instrument requirements:

Preferred Blood Glucose Meter to be used with the Prodigy No Coding Test Strips.

**I. Device Description:**

The Prodigy Preferred Blood Glucose Monitoring System consists of a meter and test strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions. The Prodigy Control Solutions (levels, low and high)

were previously cleared under 510(k) submission k073118). Level Low is included with the Prodigy Preferred BGMS. The two control solutions can be purchased separately.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Prodigy Voice Blood Glucose Monitoring System
2. Predicate 510(k) number(s):  
k073118
3. Comparison with predicate:

The Preferred Blood Glucose Monitoring System has the following similarities and differences to the predicate device:

<b>Items</b>	<b>Predicate Device</b>	<b>Candidate Devices</b>
Brand Name	Prodigy Voice Blood Glucose Monitoring System (k073118)	Prodigy Preferred Blood Glucose Monitoring System (k122338)
Indications for Use	The Prodigy Voice Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood as an aid in monitoring the effectiveness of diabetes control program.	Same
Speaking function	Yes	No
Enzyme	Glucose Oxidase	Same
Detection method	Amperometric method	Same
Battery life	Over 1000 tests	Same
Power	Two 1.5V AAA alkaline batteries	One 3V CR2032 batteries
Auto turn-off	After 3 minutes without action	Same
Test range	20 mg/dL to 600 mg/dL	Same
Operating conditions	50°F to 104°F (10°C to 40°C), below 85% R.H. (non-condensing)	Same
Storage/Transportation conditions	39.2 to 115 °F (4 to 46 °C), below 85% R.H	Same
External	USB Data port	Data port (non-USB)

Items	Predicate Device	Candidate Devices
Brand Name	Prodigy Voice Blood Glucose Monitoring System (k073118)	Prodigy Preferred Blood Glucose Monitoring System (k122338)
output		
Weight	68g (2.4 oz) with batteries	45g (1.6 oz) with batteries
Dimension	95 mm (L) x 55 mm (W) x 18 mm (H)	71 mm (L) x 60 mm (W) x 19 mm (H)
Memory	450 measurements with date and time	120 measurements with date and time
Day average	7-, 14-, 21-, 28-, 60- and 90 day average glucose result	7-, 14-, 21- and 28 day average glucose result
Glucose units	Either mg/dL or mmol/L	Same
Test strip	Code number checking	Same
Temperature compensation	Automatic compensation with built-in thermister	Same
Sample volume	0.7 µl	Same
Reaction time	7 seconds	Same

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

IEC 60601-1-2:2007 Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance EMC

ISO 14971 Application of risk management to medical devices

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

EP5-A: Evaluation of precision performance of clinical chemistry devices

EP9-A2: Method comparison and bias estimation using patient samples; approved guideline

**L. Test Principle:**

The Preferred Blood Glucose Monitoring System uses an electrochemical method. It is based on the quantitative measurement of glucose in whole blood using amperometric method, which detects the current produced from glucose oxidation. Glucose in the sample mixes with specific chemicals on the test strip producing a small amount of electrical current. The meter measures the current and displays the corresponding blood glucose level in the sample. 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:*

The repeatability study was performed by a single operator in one day using lithium heparin anti-coagulated venous whole blood at five different glucose concentrations. The final glucose concentrations for the blood sample were confirmed by YSI 2300. Each sample was tested ten times on ten meters using three lots of test strips (each meter tested with three test strips lots). Thirty measurements were obtained per meter and three test strip lots, and a glucose concentration (N=300 per concentration level). The results are summarized below:

**Repeatability summary**

Glucose Concentrations (mg/dL)	30 to 50	51 to 110	111 to 150	151 to 250	251 to 400
YSI (mg/dL)	42.3	79.8	132	198	325
Overall mean (mg/dL)	42.4	78.5	134.3	195.4	329.4
Overall SD (mg/dL)	2.3	2.7	3.4	5.0	9.2
Overall CV (%)	5.5	3.4	2.5	2.6	2.8

Intermediate precision studies were performed by a single operator using three levels of control solutions. Each sample was tested ten times on ten meters using three lots of test strips for ten days (N=1000 per concentration level).

**Intermediate Precision summary**

Control Solutions	Level 1	Level 2	Level 3
YSI (mg/dL)	40.8	121	351
Overall mean (mg/dL)	40	120	350
Overall SD (mg/dL)	2.0	4.1	9.9
Overall CV (%)	5.0	3.4	2.8

*b. Linearity/assay reportable range:*

Thirteen lithium heparin anti-coagulated venous whole blood samples were prepared to cover the device measuring range. Glucose concentrations (15.1, 21.1, 50.3, 90.8, 150, 248, 305, 352, 401, 457, 505, 601 and 621 mg/dL) were confirmed by the YSI 2300 glucose analyzer. The study was performed using ten meters and three lots of test strip in replicates of ten per meter (N=103 per test strip lot). The results are summarized below:

Strip lot	N	R2	Linear Regression
1	103	0.9980	$y=0.9757x+4.1230$
2	103	0.9979	$y=0.9702x+4.9569$
3	103	0.9980	$y=0.9810x+3.1466$
combined	309	0.9980	$y=0.9822x+2.8123$

The measurement range of the Preferred Blood Glucose Monitoring Systems is 20 to 600 mg/dL.

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

The Preferred Blood Glucose Monitoring System is traceable to NIST SRM#917b Clinical Dextrose standard.

Prodigy Control Solutions: The Prodigy Control Solutions were cleared under k073118. Please see k073118 for traceability, stability, and expected value information. The shelf life of Prodigy Control Solutions is 18 months for closed vials, and 90 days after a vial has been opened when stored tightly closed at temperatures between 39°F to 86°F (4°C to 30°C), and between 10% to 90% R.H.

Prodigy Test Strip Stability - The Prodigy No Coding Test Strips were cleared under k073118. The Stability study protocol and acceptance criteria for opened and closed vial stability provided supports the stability claims of 24 months shelf-life for unopened test strip vials, and of 3 months after opening when stored at temperatures between 39.2°F to 104°F (4°C to 40°C) and at humidity conditions between 10% to 85% R.H.

d. *Detection limit:*

The reportable range is 20 to 600 mg/dL based on the linearity/assay reportable range study above (section M.1.b).

e. *Analytical specificity:*

Interference study was designed according to CLSI EP7-A2 guideline.

Twenty four potential endogenous and exogenous interfering substances were evaluated by spiking lithium heparin anti-coagulated venous whole blood with three levels of glucose concentrations within the ranges 50 – 100, 200 - 275 and 400 -500 mg/dL (measured by YSI). The blood samples were spiked with the potentially interfering compounds and tested on five meters using three test strip lots. Several concentrations of the interfering substances were tested. The interferent concentrations tested in this study were higher than the therapeutic and toxic levels. Bias was calculated as the individual percent difference in glucose reading between the test (individual measurements) and control (mean value) concentration groups. Significant interference is defined by the sponsor as a bias  $\geq \pm 10\%$  of the test samples from the control group.

The sponsor claims no significant interference (< 10% difference) for the substances and concentrations shown in the table below for both the devices:

<b>Interferent</b>	<b>Concentration (mg/dL) tested</b>
Acetaminophen	15.0
Ascorbic acid	5.0
Salicylate	60.0

Galactose	900.0
Maltose	900.0
Xylose	100.0
Lactose	100.0
Cholesterol	500.0
Creatinine	30.0
Dopamine	10.0
Ephedrine	10.0
L-Dopa	10.0
Methyl-Dopa	3.0
Gentisic acid	10.0
Glutathione	53.0
Hydroxyurea	4.0
Ibuprofen	50.0
Tetracycline	10.0
Tolazamide	100.0
Tolbutamide	70.0
Triglycerides	2000.0
Urea	600
Uric acid	14.0
Bilirubin	90.0

No obvious interference was observed with the interfering substances at therapeutic or physiological levels tested at low, medium or high glucose levels. Elevated blood triglyceride, Reducing substances such as uric acid and ascorbic acid, Acetaminophen, Dopa, Methyl-Dopa, L-Dopa, and Tolbutamide (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

Accuracy study was performed by healthcare professional using capillary whole blood from the fingers, palm, forearm, upper arm, thigh and calf of 100 patients. The samples (concentration range tested from 52.9 to 388 mg/dL) were tested in singlicate using two meters and one lot of test strips (n = 2 per sample). In addition, the sponsor tested ten altered venous samples to include five samples with glucose concentration between 40.0 to 48.9 mg/dL, and another five samples with glucose concentration between 437 to 449 mg/dL. Venous blood samples from each participant were collected in parallel to measure the plasma glucose concentration by YSI. Hematocrit of each sample was determined. All capillary blood sample results were

compared to YSI. The studies met ISO 15197:2003 accuracy criteria, e.g. 95% of glucose results < 75 mg/dL were within  $\pm 15$  mg/dL, and for samples  $\geq 75$  mg/dL, 95% of results were within  $\pm 20\%$  of the reference method. Results are summarized below:

Regression Analysis Professional Testing on BGMS vs YSI – Finger testing with real patient samples and ten manipulated samples (N=220)

	Slope	Intercept	R <sup>2</sup>
Finger	1.004	1.1953	0.979

Healthcare Professional testing vs YSI < 75 mg/dL – Finger testing with real patient samples and ten manipulated samples (N=110)

Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL
13/16 (81%)	16/16 (100%)	16/16 (100%)

Healthcare Professional testing vs YSI < 75 mg/dL – Finger testing with real patient samples and ten manipulated samples (N=110)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
42/94 (45%)	75/94 (80%)	94/94 (100%)	94/94 (100%)

Regression Analysis Professional Testing on BGMS vs YSI (N=200)

	Slope	Intercept	R <sup>2</sup>
Finger	1.0003	1.8319	0.9782
Palm	1.0236	-0.8994	0.9661
Forearm	1.0103	0.1763	0.9701
Upper arm	0.9967	2.7246	0.954
Calf	1.0201	-2.286	0.9649
Thigh	1.0609	8.8967	0.9717

Healthcare Professional testing vs YSI < 75 mg/dL (N=100)

	Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL
Finger	10/11 (91%)	11/11 (100%)	11/11 (100%)
Palm	6/11 (55%)	11/11 (100%)	11/11 (100%)
Forearm	5/11 (45%)	9/11 (82%)	11/11 (100%)
Upper arm	5/11 (45%)	8/11 (73%)	11/11 (100%)
Calf	4/11 (36%)	11/11 (100%)	11/11 (100%)
Thigh	6/11 (55%)	10/11 (91%)	11/11 (100%)

Healthcare Professional testing vs YSI  $\geq 75$  mg/dL

	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
Finger	38/89 (43%)	70/89 (79%)	89/89 (100%)	89/89 (100%)
Palm	36/89 (40%)	62/89 (70%)	79/89 (89%)	87/89 (98%)
Forearm	33/89 (37%)	61/89 (69%)	82/89 (92%)	87/89 (98%)
Upper arm	30/89 (34%)	56/89 (63%)	74/89 (83%)	86/89 (97%)
Calf	28/89 (31%)	62/89 (70%)	79/89 (89%)	89/89 (100%)
Thigh	33/89 (37%)	60/89 (69%)	74/89 (83%)	86/89 (97%)

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):*

Lay User Performance Study:

Lay user studies for fingerstick, palm, forearm, upper arm, calf and thigh were performed by 150 lay users and healthcare professional using fresh capillary blood samples. Labeling was provided only in English and users followed it to perform the testing. The lay user first performed the testing followed by the healthcare professional of the finger, palm, forearm, upper arm, calf and thigh. Then, immediately after the above tests were completed (within 5 minutes), venous whole blood samples were collected in EDTA tubes, plasma was separated, and tested on YSI. The samples were tested using two meters and one lot of test strips (out of 3 lots in use alternatively). All results were compared to the YSI. The studies met ISO 15197:2003 accuracy criteria, e.g. 95% of glucose results  $< 75$  mg/dL were within  $\pm 15$  mg/dL, and for samples  $\geq 75$  mg/dL, 95% of results were within  $\pm 20\%$  of the reference method. Results are summarized below:

Regression Analysis Lay User testing on BGMS vs YSI (N=150)

	Slope	Intercept	R <sup>2</sup>
Finger	1.0136	-3.7813	0.9705
Palm	1.0211	-4.4124	0.9689
Forearm	1.0157	-4.9605	0.9662
Upper arm	0.9778	2.0352	0.9567
Calf	0.9776	2.0215	0.9575

Thigh	1.0039	-1.3189	0.9561
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Lay User testing vs YSI < 75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	12/21 (57%)	20/21 (95%)	21/21 (100%)
Palm	12/21 (57%)	19/21 (90%)	21/21 (100%)
Forearm	12/21 (57%)	19/21 (90%)	21/21 (100%)
Upper arm	9/21 (43%)	18/21 (86%)	21/21 (100%)
Calf	8/21 (38%)	20/21 (95%)	21/21 (100%)
Thigh	8/21 (38%)	20/21 (95%)	21/21 (100%)

Lay User testing vs YSI ≥ 75 mg/dL

	Within ± 5%	Within ± 10%	Within ± %15	Within ± 20%
Finger	54/129 (42%)	88/129 (68%)	123/129 (95%)	128/129 (99%)
Palm	56/129 (43%)	88/129 (68%)	113/129 (88%)	125/129 (97%)
Forearm	49/129 (38%)	88/129 (68%)	115/129 (89%)	128/129 (99%)
Upper arm	39/129 (30%)	82/129 (64%)	106/129 (82%)	128/129 (99%)
Calf	44/129 (34%)	79/129 (61%)	113/129 (88%)	127/129 (98%)
Thigh	35/129 (27%)	78/129 (60%)	109/129 (84%)	128/129 (99%)

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

As per the American Diabetes Association (ADA) recommendation, the sponsor has included the following target values for people without diabetes:

Pre-prandial plasma glucose concentration (before meal) 70 to 100 mg/dL

Post-prandial plasma glucose concentration < 140 mg/dL  
(1-2 hours after starting a meal)

Source: *American Diabetes Association Standards of Medical Care in Diabetes (2012) Diabetes Care, 35 (Supp 1), S11-S63.*

**N. Instrument Name:**

Prodigy Preferred Blood Glucose meter

**O. System Descriptions:**

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 0.7 µL.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes  X or No

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes  or No

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:

The glucose test is intended to be used with capillary whole blood from the finger, the palm, the forearm, the upperarm, the thigh and the calf. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

The Prodigy Preferred Blood Glucose meter does not require coding.

6. Quality Control:

Glucose control solutions at two concentration levels can be run with this device. The meter has to be set in control solution test mode to prevent control results from being stored in the internal memory as patient result. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the control solutions vial label. The user is cautioned not to use the meter if the control result falls outside these ranges. Low level control solution is provided with the complete kit. The meter only kit label states that control solutions are not included, and must be purchased separately.

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

1. A usability study was performed to assess the readability of the labeling by recruiting 150 lay users (aged 25-75 yrs old) who were provided with the test kit containing labeling in English for the US market. Participants varied in age, education, country of origin, and both men (n

= 110) and women (n = 40) were included in the study. These lay users also completed a questionnaire to indicate whether the device is easy to use and the Instructions for use were written in a way that makes it easy to use. The majority of the users responded that the device is very easy to use.

2. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User Guide, test strip package insert, quick reference guide and control solution package insert) were written at grade levels ranging from 7.0<sup>th</sup> to 8.0<sup>th</sup> grade.
3. Customer service is available 24 hours, 7 days a week. The telephone number is 1-800-243-2636 for customer support.
4. The effect of different hematocrit levels on the accuracy of the Prodigy Blood Glucose Monitoring System was evaluated using ten meters in duplicates using two lots of test strips. Blood samples (anticoagulant lithium heparin) at six hematocrit levels from 20% to 60% (15, 20, 30, 40, 60 and 65%) were evaluated in five concentrations of glucose of approximately 42.8, 77.5, 127, 200 and 317 mg/dL (measured by YSI). Individual glucose measurements were compared to the reference method (YSI) and 40% HCT. The sponsor calculated individual %bias vs. YSI and 40% HCT. Results demonstrated that hematocrit levels between 20 to 60% do not significantly interfere with glucose measurements.
5. Minimum sample volume study was provided by testing a range of volumes between 0.5 to 1.5  $\mu$ L (0.5, 0.6, 0.7, 0.8, 1.0, 1.2 and 1.5  $\mu$ L) of heparinized venous blood samples (at five glucose concentration levels – 40, 77, 112, 177 and 336 mg/dL, measured by YSI) using eight meters and two lots of test strips. Individual glucose measurements were compared to the reference method (YSI), and percent bias were calculated. Results demonstrated that the Prodigy Meter and Prodigy No Code Test Strips require a minimum sample volume of 0.7  $\mu$ L for obtaining accurate results.
5. Temperature and humidity operating conditions were evaluated for temperatures ranging from 50°F to 104°F (10°C to 40°C) and relative humidity between 10 to 85% R.H. using three glucose concentration levels of heparinized venous blood (49, 150 and 320 mg/dL, measured by YSI), seven meters and three lots of test strips. Individual glucose measurements were compared to the reference method (YSI), and percent bias were calculated. Results demonstrated that glucose measurements on the Preferred BGMS were not affected at temperatures ranging from 50°F to 104°F (10°C to 40°C) and relative humidity between 10 to 85% R.H.
6. The effect of altitude on the accuracy of the device was evaluated on the Prodigy Preferred Blood Glucose Monitoring System with three meters and three test strip lots. A range of altitudes (298, 2920, 4790, 6234, 8536 and 11161 feet) was tested using heparinized venous blood samples (at five glucose concentration levels – 49, 120, 152, 253 and 400 mg/dL, measured by YSI). Individual glucose measurements were compared to the reference method (YSI), and percent bias were calculated. Results demonstrated that glucose measurements on the Preferred BGMS were not affected up to an altitude of 11,161 feet (3,402 meters).

7. The Preferred Blood Glucose Monitoring System is intended for home use by single person. Disinfection studies were performed on the Preferred meter to determine the robustness of the meter to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV). Dispatch® Hospital Cleaner Disinfectant Towel with Bleach (EPA Reg. No. 56392-8) was validated, demonstrating complete inactivation of live virus for use with the Preferred meter. The sponsor demonstrated that there was no change in performance or in the external materials of the Preferred meter after 5000 cleaning and disinfection cycles to simulate an estimated 31 cleaning and disinfection cycles per week over three years of use at home by a single person,. Labeling has been reviewed for adequate instructions on the validated cleaning and disinfection procedures.
8. EMC testing was evaluated and certified by AUDIX Technology Corporation and a certificate of conformity was issued to Prodigy Diabetes Care LLC on December 25, 2012.

**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.