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

A. 510(k) Number:

k122340

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose from the finger, forearm, upper arm, palm, calf and thigh

D. Type of Test:

Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:

Prodigy Diabetes Care, LLC

F. Proprietary and Established Names:

Prodigy Choice Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NBW - Glucose test system	Class II	862.1345	Clinical Chemistry (75)
CGA – Glucose Oxidase, Glucose	Class II	862.1345	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below

2. Indication(s) for use:

The Prodigy Choice 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, palm, upper-arm, calf or thigh. The Prodigy Choice Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Prodigy Choice 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 Choice 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 Choice Test Strips are for use with the Prodigy Choice Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, palm, upper-arm, calf or thigh.

3. Special conditions for use statement(s):

- For over-the-counter use
- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients
- Prodigy Choice Blood Glucose Meter is for single-patient use only
- Alternative site testing (AST) testing should only be done during steady-state times (when glucose is not changing rapidly).
- AST should not be used to calibrate continuous glucose monitors (CGMs).
- AST should not be used for insulin dose calculations.

The following warning appears in the test strip insert, meter kit box, and owner's manual regarding the low performance in lay-user accuracy:

CAUTION

Blood Glucose Meter Accuracy is the most important criteria in determining glucose meter quality. The Prodigy Choice® Blood Glucose Monitoring System is less accurate than most other blood glucose meters sold today. The Prodigy Choice® meter does not provide reliable accuracy readings beyond the following margins of error:
For glucose concentrations < 75 mg/dL, 95% of the results shall be within ± 15 mg/dL.
For glucose concentrations > 75 mg/dL, 95% of the results shall be within ± 20%.

DO NOT USE THE PRODIGY CHOICE® TO CALCULATE INSULIN DOSAGES.

DO NOT USE THE PRODIGY CHOICE® TO CALIBRATE CONTINUOUS GLUCOSE MONITORS

The following warning appears on the test strip box:

The Prodigy Choice® Blood Glucose Monitoring System is less accurate than most other blood glucose meters sold today.

DO NOT USE THE PRODIGY CHOICE® TO CALCULATE INSULIN DOSAGES.
DO NOT USE THE PRODIGY CHOICE® TO CALIBRATE CONTINUOUS GLUCOSE MONITORS.

4. Special instrument requirements:

   Prodigy Choice Blood Glucose Meter

I. Device Description:

The Prodigy Choice Blood Glucose Monitoring System is marketed as a meter only with a carrying case, battery, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card. The Prodigy Choice Blood Glucose Monitoring System is also marketed as a meter kit with a carrying case, battery, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card, Prodigy Lancing Device, Prodigy Lancets, Prodigy Choice Test Strips, and Prodigy Control Solution (1 level).

Prodigy Choice Blood Glucose Monitoring System consists of the following:

Prodigy Choice Blood Glucose Meter

Prodigy Choice Test Strips (Calibration code embedded on strip) - Glucose oxidase (*Aspergillus sp.*)

Prodigy Control Solution - (2 levels: low 30-50 mg/dL and high 200-300 mg/dl): Previously cleared in k060467

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Prodigy Voice BGMS

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

   k073118

3. Comparison with predicate:

	Candidate Device	Predicate (k073118)
Type	Prodigy Choice Blood Glucose Monitoring System	Prodigy Voice Blood Glucose Monitoring System
Indications for Use/Intended Use	The Prodigy Choice 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 people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control. 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.	Same
Detection Method	Amperometry	Same
Sample Type	Capillary whole blood	Same
Sample Sites	Finger, palm, forearm, upper-arm, calf, thigh	Same
Sample Volume	0.7 µL	Same
Measurement Range	20-600 mg/dL	Same
Test Strip	User verifies code embedded on test strip and displayed on screen matches the test strip vial	Same
Speaking Function	No	Yes
Reaction Time	7 sec	Same
Reagent Enzyme	Glucose Oxidase	Same
Day Average	7, 14, 21, 28	7, 14, 21, 28, 60, 90
Identification of Control Solution and Results	User manually selects control solution button	
Hematocrit Range (%)	20 - 60%	Same

Test Strip Stability (open-vial)	90 days	Same

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

ISO 15197:2003: *In Vitro Diagnostic Test Systems-Requirements for Blood Glucose Monitoring Systems for Self-Testing in Managing Diabetes*

NCCLS EP9-A: Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline

NCCLS EP5-A: Evaluation of Precision Performance of Quantitative Measurement Methods; Approvided Guideline

ISO 14971: Medical Devices – Application of risk management to medical devices

60601-1-2: Medical electrical equipment – Part 1-1: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

L. Test Principle:

The test is based on the measurement of electrical current generated by the reaction of capillary whole blood glucose with glucose oxidase of the test strip. The meter measures the strength of the current which is proportional to the concentration of glucose present and displays the corresponding blood glucose level.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

   Repeatability (Within-run)

   The sponsor performed within-run precision studies using venous whole blood samples adjusted to give the following five glucose concentrations (30 - 50, 51 - 110, 111 - 150, 151 - 250, and 251 – 400 mg/dL). Each glucose level was analyzed in replicates of 10, using three test strip lots, and 10 meters for a total of 30 tests per each glucose level for each meter. The results are summarized below:

Lot 1	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL

YSI	43.1	81.8	135	201	318
Mean	43.3	80.4	137.7	197.4	321.6
SD	2.1	2.5	3.3	4.8	9.4
%CV	5.1	3.1	2.4	2.4	2.9
n	100	100	100	100	100

Lot 2	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL
YSI	43.1	81.8	135	201	318
Mean	43.2	81.1	137.7	197.6	323.4
SD	2.2	2.5	3.5	5.1	9.5
%CV	5.1	3.1	2.6	2.6	2.9
n	100	100	100	100	100

Lot 3	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL
YSI	43.1	81.8	135	201	318
Mean	43.7	80.3	137.8	198.7	322.2
SD	2.3	2.4	3.4	5.1	9.4
%CV	5.4	2.9	2.5	2.6	2.9
n	100	100	100	100	100

The combined within-run precision data for all three lots is described in the table below:

	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
[Conc.]	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL
Grand Mean (mg/dL)	43.4	80.6	138	198	322
Pooled SD (mg/dL)	2.3	2.5	3.4	5.0	9.4
Pooled %CV	5.2	3.1	2.5	2.5	2.9
n	300	300	300	300	300

Intermediate Precision (Between Run)

Between Run imprecision was evaluated by testing 3 levels of control solutions (analyzed separately) using 3 test strip lots. Lot 1: 10 replicates using 5 different meters for 10 days, Lots 2 and 3: 5 replicates using 5 different meters for 10 days.

Each of the control solutions were tested on all 5 meters each day. The results are summarized below.

Lot 1	Low	Normal	High
Conc.	30 - 50	96 - 144	200-300
YSI	40.7	120	261
Mean	40.0	119.1	259.8
SD	1.98	3.9	11.8
%CV	4.9	3.3	4.5
n	500	500	500

Lot 2	Low	Normal	High
Conc.	30 - 50	96 - 144	200-300
YSI	40.7	120	261
Mean	40.0	119.2	259.8
SD	1.98	4.4	11.9
%CV	5.0	3.7	4.6
n	250	250	250

Lot 3	Low	Normal	High
Conc.	30 - 50	96 - 144	200-300
YSI	40.7	120	261
Mean	40.1	119.0	259.5
SD	2.03	4.3	11.3
%CV	5.1	3.6	4.4
n	250	250	250

The combined intermediate precision data for all three lots is described in the table below:

Control Level	1	2	3	n
[Conc.] mg/dL	30 - 50	96 - 144	200-300	
Grand Mean (mg/dL)	40	119	260	1000
Pooled SD (mg/dL)	2.0	4.1	11.4	1000
Pooled %CV	5.0	3.5	4.4	1000

b. Linearity/assay reportable range:

Linearity was evaluated using ten meters, three test strip lots and 13 glucose venous blood samples ranging in glucose concentrations (as measured by YSI) of 15, 22, 50, 90, 149, 251, 300, 349, 403, 455, 500, 601, 620 mg/dL. Each level was measured in 10 replicates per lot, per level for a total of 390 samples. Pooled and per lot data is below.

Lot	1	2	3
N	130	130	130
Slope	0.98	1.00	0.99
y-intercept (mg/dL)	3.74	2.40	2.67
Correlation coefficient	1.00	1.00	1.00

Pooled	
N	390
Slope	0.99
y-intercept (mg/dL)	2.94
Correlation coefficient	1.00

The results of the study support the sponsor's claimed glucose measurement range of 20 - 600 mg/dL.

c. *Traceability, Stability (21 CFR § 211.166), Expected values (controls, calibrators, or methods):*

Traceability: The assay is traceable to NIST SRM#917b

Controls: Open and closed vial stability was established in k060467.

Test Strip Stability

Protocol, acceptance criteria and summary results of real-time open and closed-vial, stability studies were performed on three lots of test strips at 4, 25, and 40 °C; with 10 and 85% relative humidity). Protocol, acceptance criteria support shelf-life claim (24 months), open-vial claim (90 days) in temperatures of 39 to 104 °F (4 to 40 °C) and 10 - 85% RH.

d. *Detection limit:*

See section M.1.b (linearity)

The reportable range is 20 to 600 mg/dL based on linearity/reportable range studies above. The low and high detection limits for this device have been set at 20 and 600

mg/dL. Readings below 20 mg/dL and above 600 mg/dL will indicate a "Lo" and "Hi" on the meter display, respectively.

e. Analytical specificity:

Interference

An interference study was performed to evaluate the effects of endogenous and exogenous substances on the glucose test results generated by the Prodigy Choice Blood Glucose Monitoring System. Venous blood samples were collected into Lithium heparin tubes. Three glucose levels were achieved (50-100, 200-275, and 400-500 mg/dL) by adding a dextrose solution to the blood pool. Potential interferents were aliquotted into samples. The control pool (without an interfering compound) and test pool were measured by YSI and then on five meters using three test strip lots for each glucose concentration. The results are summarized below to show the highest concentration without significant interference (defined by the sponsor as ±10% bias).

Substance	Highest concentration without interference (mg/dL)
Acetaminophen	15
Ascorbic Acid	5.0
Bilirubin	90
Cholesterol	500
Creatinine	30
Dopamine	10
Galactose	900
Gentisic Acid	10
Glutathione	53
Hydroxyurea	4.0
Ibuprofen	50
L-dopa	10
Maltose	900
Methyldopa	3.0
Salicylate	60
Tolazamide	100
Tolbutamide	70
Triglycerides	2000
Uric Acid	14
Xylose	100

f. Assay cut-off:

- Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy

To assess system accuracy, results from the Prodigy Choice Blood Glucose Monitoring System were compared to a reference method, YSI. Finger, palm, forearm, upper-arm, calf, and thigh capillary samples were collected by healthcare professionals from 100 participants with unaltered glucose concentrations ranging from 53.4 – 394 mg/dL (according to reference) were tested using three test strip lots. To obtain blood glucose concentrations <50 mg/dL and > 400 mg/dL, samples were allowed to glycolize or were spiked to achieve the desired glucose concentration. Ten samples were altered (5 glycolyzed, 5 spiked). The results relative to YSI are summarized in the tables below:

Finger

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
4/14 (29%)	8/14 (57%)	14/14 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
29/86 (34%)	49/86 (57%)	67/86 (78%)	85/86 (99%)
Accuracy of Prodigy Choice (**HCP**) compared to YSI using capillary whole blood (**fingerstick**)			
		n	100
		Slope	0.98
		y-int. (mg/dL)	1.49
		r^2	0.95
		Range (mg/dL)	53 – 394

Palm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
4/14 (29%)	11/14 (79%)	14/14 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
21/86 (24%)	48/86 (56%)	67/86 (78%)	82/86 (95%)
Accuracy of Prodigy Choice (**HCP**) compared to YSI using capillary whole blood (**Palm**)			
		n	100
		Slope	0.98
		y-int. (mg/dL)	2.70
		r^2	0.95
		Range (mg/dL)	53 – 394

Forearm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
2/14 (14%)	9/14 (64%)	14/14 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
24/86 (28%)	52/86 (60%)	76/86 (88%)	83/86 (97%)
Accuracy of Prodigy Choice (HCP) compared to YSI using capillary whole blood (forearm)			
		n	100
		Slope	1.00
		y-int. (mg/dL)	-0.28
		r^2	0.95
		Range (mg/dL)	53 – 394

Upper arm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
5/14 (36%)	9/14 (64%)	14/14 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
26/86 (30%)	50/86 (58%)	71/86 (83%)	84/86 (98%)
Accuracy of Prodigy Choice (HCP) compared to YSI using capillary whole blood (Upper arm)			
		n	100
		Slope	0.98
		y-int. (mg/dL)	1.05
		r^2	0.95
		Range (mg/dL)	53 – 394

Calf

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
2/14 (14%)	7/14 (50%)	14/14 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
26/86 (30%)	46/86 (53%)	71/86 (83%)	85/86 (99%)
Accuracy of Prodigy Choice (HCP) compared to YSI using capillary whole blood (Calf)			
		n	100
		Slope	1.00
		y-int. (mg/dL)	0.49
		r^2	0.95
		Range (mg/dL)	53 – 394

Thigh

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
7/14 (50%)	10/14 (71%)	14/14 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
21/86 (24%)	49/86 (57%)	71/86 (83%)	84/86 (98%)

Accuracy of Prodigy Choice (HCP) compared to YSI using capillary whole blood (Thigh)		
	n	100
	Slope	0.98
	y-int. (mg/dL)	3.55
	r^2	0.96
	Range (mg/dL)	53 – 394

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):

User Performance Study

To assess the performance of the Prodigy Choice Blood Glucose Monitoring System in the hands of the lay-users the sponsor performed a study with 151 lay-user participants, who collected 151 each of finger, palm, forearm, upper-arm, calf, and thigh capillary samples using only English-written labeling materials with no other instructions or coaching. Results from 3 test strip lots and 300 meters were analyzed by comparing blood glucose results from the Prodigy Choice meter obtained by the lay-user against the YSI reference value. The glucose concentration of the samples ranged from 50.3 to 355 mg/dL as measured by YSI. The results are summarized below.

The data obtained in the lay user study were not as accurate as meters on the market. Therefore the sponsor added the following caution to the test strip insert, meter manual, and the meter kit box:

CAUTION

Blood Glucose Meter Accuracy is the most important criteria in determining glucose meter quality. The Prodigy Choice® Blood Glucose Monitoring System is less accurate than most other blood glucose meters sold today. The Prodigy Choice® meter does not provide reliable accuracy readings beyond the following margins of error:
For glucose concentrations < 75 mg/dL, 95% of the results shall be within ± 15 mg/dL.
For glucose concentrations > 75 mg/dL, 95% of the results shall be within ± 20%.
DO NOT USE THE PRODIGY CHOICE® TO CALCULATE INSULIN DOSAGES.

DO NOT USE THE PRODIGY CHOICE® TO CALIBRATE CONTINUOUS GLUCOSE MONITORS

The following warning appears on the test strip box:

The Prodigy Choice® Blood Glucose Monitoring System is less accurate than most other blood glucose meters sold today.

DO NOT USE THE PRODIGY CHOICE® TO CALCULATE INSULIN DOSAGES.
DO NOT USE THE PRODIGY CHOICE® TO CALIBRATE CONTINUOUS GLUCOSE MONITORS.

Finger

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
2/15 (13%)	11/15 (73%)	15/15 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
45/136 (33%)	70/136 (51%)	104/136 (76%)	131/136 (96%)

Accuracy of Prodigy Choice (**Lay-user**) compared to YSI using capillary whole blood (**fingerstick**)		
	n	151
	Slope	1.0238
	y-int. (mg/dL)	-3.5685
	r^2	0.9417
	Range (mg/dL)	50.3 - 355

Palm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
4/15 (27%)	14/15 (93%)	15/15 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
31/136 (23%)	64/136 (47%)	98/136 (72%)	132/136 (97%)
Accuracy of Prodigy Choice (**Lay-user**) compared to YSI using capillary whole blood (**Palm**)			
		n	151
		Slope	0.9919
		y-int. (mg/dL)	-1.041
		r^2	0.9259
		Range (mg/dL)	50.3 - 355

Forearm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
8/15 (53%)	10/15 (67%)	15/15 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
28/136 (21%)	73/136 (54%)	107/136 (79%)	130/136 (96%)
Accuracy of Prodigy Choice (Lay-user) compared to YSI using capillary whole blood (forearm)			
		n	151
		Slope	0.9994
		y-int. (mg/dL)	-2.8697
		r^2	0.9376
		Range (mg/dL)	50.3 - 355

Upper Arm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
5/15 (33%)	11/15 (73%)	15/15 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
51/136 (38%)	94/136 (69%)	123/136 (90%)	134/136 (99%)
Accuracy of Prodigy Choice (Lay-user) compared to YSI using capillary whole blood (Upper arm)			
		n	151
		Slope	0.9645
		y-int. (mg/dL)	-3.221
		r^2	0.9718
		Range (mg/dL)	50.3 - 355

Calf

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
3/15 (20%)	9/15 (60%)	15/15 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
61/136 (45%)	104/136 (76%)	128/136 (94%)	136/136 (100%)
Accuracy of Prodigy Choice (Lay-user) compared to YSI using capillary whole blood (Calf)			
		n	151
		Slope	0.97
		y-int. (mg/dL)	-3.085
		r^2	0.9734
		Range (mg/dL)	50.3 - 355

Thigh

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
5/15 (33%)	10/15 (67%)	15/15 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
56/136 (41%)	99/136 (73%)	127/136 (93%)	135/136 (99%)
Accuracy of Prodigy Choice (Lay-user) compared to YSI using capillary whole blood (Thigh)			
		n	151
		Slope	1.0194
		y-int. (mg/dL)	-6.7856
		r^2	0.9674
		Range (mg/dL)	50.3 - 355

4. Clinical cut-off**:**

- Not applicable

5. Expected values/Reference range:

Status	Range
Preprandial plasma glucose (before a meal)	70-100 mg/dL
Postprandial plasma glucose (after a meal)	<140 mg/dL

American Diabetes Association. Standards of medical care in diabetes – 2012. Diabetes Care. 2012;35(Supp 1):S11-S63

N. Instrument Name:

Prodigy Choice meter

O. System Descriptions:

1. Modes of Operation:

   Each 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 _____ or No __X___.

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

   Yes _____ or No __X___.

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, palm, forearm, upper-arm, calf and thigh only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The meter is an auto-coding meter. No coding is required by the user. The user is required to verify that the code displayed on the meter and read off the test strip accurately reflects the code on the test strip vial.

6. Quality Control:

   Two levels of control glucose solution are available. One level is sold with the

meter as a kit. The user has to change the setting on the meter to control so that the result is not saved.

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

1. Hematocrit Study: The effect of different hematocrit levels on the performance of the Prodigy Choice Blood Glucose System was evaluated using venous whole blood samples with hematocrit levels 15, 20, 30, 40, 60 and 65 %,, and spiked or glycolyzed to achieve 6 glucose concentrations ranging from 50 to 500 mg/dL (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL). Each sample was then tested 20 times using 10 Prodigy Choice meters and two lots of test strips. The meter values were compared with those obtained from average YSI analyzer values at the tested hematocrit level and normal hematocrit (40%). The percent biases relative to YSI were acceptable within the claimed hematocrit range of 20 to 60%.

2. Altitude study: Venous whole blood samples collected and adjusted to obtain 5 glucose concentrations of 30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL were tested at 298, 2,920, 4,790, 6,234, 8,563, and 11,161 feet above sea level. The study included 3 meters and 3 test strip lots. Results were compared to YSI values. The results demonstrate acceptable bias and indicate acceptable performance to the claimed altitude of 11,161 ft. The sponsor has claimed an altitude of 10,742 feet in their labeling.

3. Temperature and Humidity studies: The sponsor performed temperature and humidity studies using venous blood samples with glucose concentrations of 30-50, 96-144, and 280-420 mg/dL to evaluate temperatures ranging from 10 to 40°C (50 to 104 °F) and relative humidity from 10% to 85%. Meter results were compared to YSI values. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity, and high temperature/high humidity. No significant bias (relative to YSI) was observed with the temperature and humidity combinations tested. The results support a temperature claim of 10 to 40°C (50 to 104 °F) with relative humidity of 10 to 85%.

4. Sample Volume: The sponsor performed a study to verify the test strip minimum sample volume requirement (0.7 µL) and the test strip fill error requirement established for the Prodigy Choice Blood Glucose Monitoring System. Blood samples with glucose concentrations of 30-50, 51-110, 111-150, 151-250, and 251-400 mg/dL were tested at seven sample volumes (0.5, 0.6, 0.7, 0.8, 1.0, 1.2, 1.5 µL) and values obtained were compared to YSI values. Results support the claimed minimum sample volume of 0.7 µL.

5. Readability Evaluation: SMOG readability assessment was conducted and the results demonstrated that the User Manual and test strip package insert were written at the 8th grade level and below.

6. Electromagnetic compatibility (EMC) testing was performed by Audix Technology Corporation., Taipei Hsien, Taiwan. Verification of Compliance certificates were provided.. The results are for the Prodigy Preferred Meter, model Prodigy-C which is identical to the Prodigy Choice. The only difference is the location of the strip connector touch pin on the test strip.

7. Infection Control Studies: The meter is intended for single-patient use only. The Dispatch Hospital Cleaner Disinfection Towel with Bleach (EPA registration #56392-8) was used to validate disinfection efficacy using the PMA approved (P030049) HBV antigen assay demonstrating the absence of HBV antigen on meter surface coupons.

8. Robustness: The sponsor demonstrated that there was no change in performance (compared to YSI) or in the external materials of the meter after 10,950 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe). Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

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.