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

A. 510(k) Number:

K152599

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose from fingertip, forearm, upper arm, palm, calf and thigh.

D. Type of Test:

Quantitative Amperometric assay (Glucose Oxidase)

E. Applicant:

OK BIOTECH CO., LTD.

F. Proprietary and Established Names:

PRODIGY Astro Blood Glucose Monitoring System

PRODIGY Astro PRO Blood Glucose Monitoring System

G. Regulatory Information:

Device	Product Code	Classification	Regulation Section	Panel
PRODIGY Astro Blood Glucose Monitoring System PRODIGY Astro PRO 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:

   PRODIGY Astro Blood Glucose Monitoring System

   Prodigy® Astro Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from fingertip, forearm, upper arm, palm, calf or thigh. The Prodigy® Astro

Blood Glucose Monitoring System is intended to be used in the home by a single person and should not be shared. The Prodigy® Astro 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® Astro Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes, or for neonatal use. The alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

PRODIGY No Coding Test Strips are intended for use with the PRODIGY Astro blood glucose meter to measure concentration the of blood glucose in fresh capillary whole blood samples drawn from the fingertip, forearm, upper arm, palm, calf or thigh for self-testing at home.

PRODIGY Astro PRO Blood Glucose Monitoring System

Prodigy® Astro PRO Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from fingertip, forearm, upper arm, palm, calf or thigh. The Prodigy® Astro PRO Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use by healthcare professionals in healthcare professional settings as an aid to monitor the effectiveness of diabetes control. The Prodigy® Astro PRO Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes, or for neonatal use. The alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

PRODIGY PRO No Coding Test Strips are intended for use with the PRODIGY Astro PRO blood glucose meter to measure concentration the of blood glucose in fresh capillary whole blood samples drawn from the fingertip, forearm, upper arm, palm, calf or thigh. The system should only be used with single-use, auto-disabling lancing devices.

3. Special conditions for use statement(s):

   - For in vitro diagnostic use
   - The system should not be used in neonates
   - The system should not be used for diagnosis of or screening of diabetes mellitus
   - The system should not be used in critically ill patients
   - Not to be used for patients who are dehydrated, hypotensive, in shock or in a hyper-osmolar state
   - PRODIGY Astro PRO blood glucose meter should only be used with single-use, auto-disabling lancing devices
   - Alternative site sample results should NOT be used for calibrating CGMs or for insulin dosing calculations or when glucose levels may be rapidly changing or fluctuating such as after meals, exercise, or after taking insulin.
   - Hematocrit levels below 20% or above 60% can cause false results.

4. Special instrument requirements:

   PRODIGY Astro blood glucose meter

PRODIGY Astro PRO blood glucose meter

I. Device Description:

The Prodigy Astro and Astro PRO Blood Glucose Monitoring Systems consist of a meter, test strips and control solutions (level 1 and level 2) sold separately.

The two systems are marketed either as a meter only with a carrying case, batteries, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card; or as a meter kit with a carrying case, batteries, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card, Prodigy Lancing Device (for the single-patient use version), Prodigy Lancets, Prodigy test strips, and Control Solution.

The Prodigy/Prodigy PRO No Coding Test Strips were previously evaluated as a component of the Prodigy Preferred Blood Glucose Monitoring System (k122338).

The Prodigy Control Solutions were previously cleared in k122338.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   PRODIGY AutoCode Eject Blood Glucose Monitoring System

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

   K141914

3. Comparison with predicate:

Similarities and Differences		
Item	**Predicate Device** PRODIGY AutoCode Eject Blood Glucose Monitoring System (k141914)	**Candidate Devices** Prodigy Astro Blood Glucose Monitoring System and Prodigy Astro PRO Blood Glucose Monitoring System (k152599)
Indications for Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood from fingertip, forearm, upper arm, palm, calf or thigh as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Speaking function	Yes	No

Use Setting	At home for single patient use only	Prodigy Astro Blood Glucose Monitoring System is for single patient use at home. Prodigy Astro PRO Blood Glucose Monitoring System is for multiple patient use in professional healthcare settings.
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Memory	450 records with time and date	Same
Measuring range	20 - 600 mg/dL	Same
Sample type	Capillary whole blood	Same
Sample sites	fingertip, forearm, upper arm, palm, calf or thigh	Same
Sample volume	0.7 µL	Same
Sample test time	6 seconds	Same
Hematocrit range	20% - 60%	Same
Operating conditions	50-104°F, 10~85% R.H. (non-condensing)	Same
Strip storage conditions	39.2-104°F, 10~85% R.H. (non-condensing)	Same
Power Source	1.5V AAA Alkaline battery x 2	Same
Meter Size	100 mm (L) × 56 mm (W) × 23 mm (H)	108.5 mm (L) × 62.5 mm (W) × 30 mm (H)
Meter Weight	Approximately 79 g (with battery installed)	Approximately 105 g (with battery installed)

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

IEC 60601-1, Medical electrical equipment Part I. General requirements for safety (2005).

IEC 60601-1-2, Medical electrical equipment Part 2. Electromagnetic compatibility - Requirements and Tests (2007).

CLSI EP5-A: Evaluation of precision performance of quantitative measurements methods; Approved Guideline – 2nd edition (1999).

CLSI EP6-A: Evaluation of the linearity of quantitative measurement procedures: A statistical approach (2003).

CLSI EP7-A2: Interference testing in clinical chemistry; Approved guideline – 2nd edition (2005).

L. Test Principle:

The test is based on electrochemical biosensor technology and the principle of capillary action. A blood sample is drawn into the test strip by capillary action, and reacts with reagents (glucose oxidase from Aspergillus niger) on the test strip. This reaction produces an electrical current which is proportional to the concentration of glucose in the samples. The electrical current is measured by the meter and is displayed to the user as a corresponding blood glucose concentration.

M. Performance Characteristics (if/when applicable):

The Prodigy Astro Blood Glucose Monitoring System and the Prodigy Astro PRO Blood Glucose Monitoring System differ only in name and intended use (single- vs. multiple-patient use). Therefore, one set of performance data is appropriate to support both the systems. All performance studies provided here is representative performance from one of the two candidate devices.

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed within-run precision studies using venous whole blood samples spiked to five different glucose concentration levels (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400 mg/dL). Each glucose concentration level was analyzed in replicates of 10, with 3 test strip lots and 10 meters, for a total of 300 tests per each glucose level for 10 meter. Results are summarized below:

Lot 1				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 to 50	45.6	100	1.1	2.5
51 to 110	79.6	100	2.4	3.0
111 to 150	130.8	100	3.6	2.7
151 to 250	196.0	100	5.4	2.7
251 to 400	324.0	100	9.5	2.9

Lot 2				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 to 50	45.5	100	1.1	2.4
51 to 110	79.6	100	2.4	3.0
111 to 150	130.1	100	3.4	2.6
151 to 250	196.5	100	5.7	2.9
251 to 400	323.1	100	9.2	2.8

Lot 3				
Glucose Level (mg/dL)	Mean (mg/dL)	n	SD (mg/dL)	%CV
30 to 50	45.4	100	1.2	2.6
51 to 110	79.3	100	2.2	2.8
111 to 150	130.7	100	3.4	2.6
151 to 250	195.6	100	5.1	2.6
251 to 400	323.0	100	9.0	2.8

Intermediate (between run) precision was evaluated using 3 levels of glucose control solutions (30 – 50 mg/dL; 96 – 144 mg/dL and 250 – 420 mg/dL) over 10 days with 3 test strip lots. For each level, on each day, 5 meters were used for testing, with 10 replicates collected per meter for a total of 50 replicates per lot for each glucose level per day.

Intermediate Precision:

Lot 1			
Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	%CV
30 - 50	39.9	2.0	5.0
96 - 144	117.0	3.5	3.0
250 - 420	261.4	7.8	3.0

Lot 2			
Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	%CV
30 - 50	40.0	2.0	5.1
96 - 144	116.9	3.5	3.0
250 - 420	261.1	7.9	3.0

Lot 3			
Glucose Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	%CV
30 - 50	40.0	2.0	5.0
96 - 144	116.9	3.5	3.0
250 - 420	261.3	7.6	2.9

b. Linearity/assay reportable range:

Linearity testing was performed using venous whole blood samples. The evaluation was conducted with 10 meters and 3 test strip lots. Samples with the following glucose concentrations (mg/dL) were prepared: 15.1, 20.0, 50.1, 92.0, 150, 250.3,

300.3, 349.8, 399.8, 449.8, 510.0, 601.3 and 630.5 (as established using a laboratory reference method (YSI 2300 analyzer)). Ten strips from each lot were used for testing at each glucose concentration for a total of n=30 tests per glucose concentration. The evaluation yielded the following regression equation based on all samples:

Lot	Slope	y-intercept	R^2
1	0.9993	1.2852	0.9998
2	1.0054	-1.352	0.9996
3	0.9942	0.5085	0.9999

The results of the study support the sponsor's claimed glucose measuring range of 20-600 mg/dL. The meter displays "Lo" with glucose values below 20mg/dL, and "HI" with glucose values over 600 mg/dL. The "Lo" and "Hi" functions were validated and demonstrated to function as intended.

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

Traceability:

The system is traceable to the NIST SRM #917c glucose reference material The method comparison study was performed using the candidate device and YSI as the reference method (see Section 2.a. above).

Control Solution Value Assignment and Stability:

Prodigy Control Solutions were previously cleared in k122338.

Stability and value assignment protocols and acceptance criteria for the two levels of control solutions (level 1 and level 2) were evaluated and found to be acceptable in k122338 to support the labeled claims: closed-vial stability of 24 months at 39-86°F and open-vial stability of 90 days when stored at the recommended storage temperature (39-86°F) or until the expiration date printed on the label, whichever comes first.

Test Strip Stability:

Stability protocols and acceptance criteria for the Prodigy No/Prodigy PRO No Coding Test Strips were evaluated in k122338 and found to be acceptable to support closed-vial stability of 24 months and open-vial stability of 90 days when test strips are stored at 39.2-104°F and 10-85% relative humidity or until the expiration date printed on the label, whichever comes first. The labeling instructs the users not to freeze the test strips.

d. Detection limit:

See linearity study in Section M1b above.

e. Analytical specificity:

Interference studies were performed by spiking endogenous and exogenous substances into venous whole blood. Each potential interferent was tested at three

glucose levels (approximately 81.5, 245, and 445 mg/dL). Fifteen replicates were measured for each test sample. Results of test samples with the potential interferent measured on the Prodigy Astro Blood Glucose Meter System were compared to samples measured on a laboratory-based reference method (YSI 2300 analyzer) and bias and percent bias were calculated. This procedure was performed for three test strip lots using five meters. The compounds at the concentrations listed below did not have significant interference (defined by the sponsor as percent bias ≤ ±10%):

Interfering substance	**Concentration with no Significant Interference**
Acetaminophen	8.0 mg/dL
Ascorbic acid	5.0 mg/dL
Aspirin	60 mg/dL
Bilirubin	90 mg/dL
Cholesterol	500 mg/dL
Creatinine	5.0 mg/dL
Dopamine	2.0 mg/dL
EDTA	360 mg/dL
Galactose	900 mg/dL
Gentisic acid	5.0 mg/dL
Glutathione	53 mg/dL
Haemoglobin	500 mg/dL
Heparin	8000 U/dL
Hydroxyurea	3.0 mg/dL
Ibuprofen	50 mg/dL
Icodextrin	13 mg/dL
L-dopa	10 mg/dL
Maltose	900 mg/dL
Methyldopa	3.0 mg/dL
Pralidoxime iodide	25 mg/dL
Salicylate	60 mg/dL
Tolazamide	50 mg/dL
Tolbutamide	400 mg/dL
Triglyceride	2,000 mg/dL
Uric acid	8.0 mg/dL
Xylose	100 mg/dL

Based on these results, the sponsor includes the following in their test strip labeling:

- Do not use the PRODIGY Self-Monitoring Blood Glucose System during or after a Xylose Absorption Test. This may falsely raise glucose results. Please check with your Doctor before using the PRODIGY Self-Monitoring Blood Glucose System.
- The system exhibits interference from Acetaminophen, ascorbic acid and Ibuprofen. If you are taking acetaminophen containing drugs (Tylenol, etc., >8.0 mg/dL in your blood), or ibuprofen containing drugs (Advil, etc., > 50.0

mg/dL in your blood) or vitamin C (ascorbic acid, > 5.0 mg/dL in your blood), you may obtain inaccurate readings from this blood glucose monitoring system. Please check with your doctor before using the PRODIGY Self-Monitoring Blood Glucose System.

- High uric acid concentrations (>8 mg/dL in your blood) may interfere with the glucose measurements with this device. If you have medical conditions that are associated with high uric acid level or hyperuricemia (e.g. gout), then please check with your Doctor before using the PRODIGY Self-Monitoring Blood Glucose System.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

To assess system accuracy, results from the Prodigy Astro Blood Glucose Monitoring System were compared to a reference method (YSI 2300 analyzer). Venous samples and capillary samples from fingerstick, forearm, palm, upper arm, calf and thigh were obtained by professional users from 100 participants with glucose concentrations ranging from 50.9 to 415 mg/dL. To obtain extreme blood glucose concentrations, six samples were altered. The meter results relative to YSI are summarized below:

Fingertip Testing

For glucose concentrations < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
11/15 (73.3%)	14/15 (93.3%)	15/15 (100%)	
For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20 %
54/85 (63.5%)	76/85 (89.4%)	84/85 (98.8%)	85/85 (100%)

Palm Testing

For glucose concentrations < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
12/15 (80%)	15/156 (100%)	15/15 (100%)	
For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
50/85 (58.8%)	76/85 (89.4%)	84/85 (98.8%)	85/85 (100%)

Forearm Testing

For glucose concentrations < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
9/15 (60%)	15/15 (100%)	15/15 (100%)	
For glucose concentrations ≥75 mg/dL			
Within ±	Within ± 10%	Within ± 15% ±	Within ± 20 %
53/85 (62.4%)	74/85 (87.1%)	82/85 (96.5%)	85/85 (100%)

Upper arm Testing

For glucose concentrations < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
10/15 (66.7%)	14/15 (93.3%)	15/15 (100%)	
For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15% ±	Within ± 20 %
55/85 (64.7%)	77/85 (90.6%)	83/85 (97.6%)	85/85 (100%)

Calf Testing

For glucose concentrations < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
10/15 (66.7%)	15/15 (100%)	15/15 (100%)	
For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20 %
51/85 (60%)	74/85 (87.1%)	81/85 (95.3%)	85/85 (100%)

Thigh Testing

For glucose concentrations < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
10/15 (66.7%)	14/15 (93.3%)	15/15 (100%)	
For glucose concentrations ≥75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within 20 %
52/85 (61.2%)	80/85 (94.1%)	84/85 (98.8%)	85/85 (100%)

Results of linear regression (N=100) are shown below:

Fingertip: $y = 0.9956x + 0.9796$; $R^2 = 0.9865$

Palm: $y = 1.0143x + 2.1599$; $R^2 = 0.9847$

Forearm: $y = 1.0187x – 2.316$; $R^2 = 0.9838$

Upper arm: $y = 1.0001x – 1.3378$; $R^2 = 0.9836$

Calf: $y = 0.9995x - 0.5912$; $R^2 = 0.9831$

Thigh: $y = 1.0239x - 2.0456$; $R^2 = 0.9873$

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 Astro Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 103 lay user participants who collected and tested samples from their own fingertip, palm, forearm, upper arm, calf and thigh. Results were analyzed by comparing blood glucose results obtained by the lay users with the Prodigy Astro Blood Glucose Monitoring System against results obtained using a laboratory reference method (YSI 2300 analyzer). The glucose concentrations in the samples ranged from approximately 55.8 to 403 mg/dL as measured by the laboratory reference method. Results are summarized in the tables below:

For glucose concentrations <75 mg/dL

Site	Within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	12/19 (63.2%)	16/19 (84.2%)	19/19 (100%)
Palm	12/19 (63.2%)	18/19 (94.7%)	19/19 (100%)
Forearm	12/19 (63.2%)	18/19 (94.7%)	19/19 (100%)
Upper arm	14/19 (73.7%)	18/19 (94.7%)	19/19 (100%)
Calf	12/19 (63.2%)	16/19 (84.2%)	19/19 (100%)
Thigh	12/19 (63.2%)	17/19 (89.5%)	19/19 (100%)

For glucose concentrations ≥ 75 mg/dL

Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Finger	51/84 (60.7%)	72/84 (85.7%)	82/84 (97.6%)	84/84 (100%)
Palm	58/84 (69.0%)	77/84 (91.7%)	81/84 (96.4%)	84/84 (100%)
Forearm	53/84 (63.1%)	74/84 (88.1%)	82/84 (97.6%)	84/84 (100%)
Upper arm	55/84 (65.5%)	78/84 (92.9%)	81/84 (96.4%)	84/84 (100%)
Calf	53/84 (63.1%)	72/84 (85.7%)	82/84 (97.6%)	84/84 (100%)
Thigh	54/84 (64.3%)	74/84 (88.1%)	81/84 (96.4%)	84/84 (100%)

Linear Regression Analysis:

Sample Site	Slope	Intercept	R^2	N
Fingertip	0.9691	1.7595	0.9774	103
Palm	0.9866	0.9495	0.9831	103
Forearm	0.9633	2.4022	0.9801	103
Upper arm	0.9989	1.4899	0.9862	103
Calf	0.9665	0.4658	0.9816	103
Thigh	0.9815	1.0802	0.9811	103

Usability Study: Users completed questionnaires regarding ease of use (on a scale of 1(much not agreeable), 2 (not agreeable), 3 (no comment), 4 (agreeable) to 5 (very agreeable)) as well as specific questions to test understanding of information in the user manual. The users of the device were able to understand and follow the instructions provided in the labeling to perform the blood glucose testing.

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The sponsor provided the following information for expected glucose values for persons

without diabetes:

The normal adult fasting blood glucose range for a nondiabetic person is Less than 100 mg/dL (5.55 mmol/L) and less than 140 mg/dL (7.77 mmol/L) up to 2 hours after meals.

Source: American Diabetes Association. Classification and diagnosis of diabetes. Sec. 2. In Standards of Medical Care in Diabetes - 2016. Diabetes Care 2016; 39 (Suppl. 1):S16.

N. Instrument Name:

PRODIGY Astro Blood Glucose Meter

PRODIGY Astro PRO 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 ____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 system is intended to be used with capillary whole blood from the finger, palm, forearm, upper arm, calf and thigh. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   Calibration is automatic. There is no user input for coding.

6. Quality Control:

   Two levels of aqueous glucose control solutions are available (sold separately) for use with this system. Instructions on how to order the control solutions are included in the user manual. The meter has a function for the user to select that they wish to run a control solution to prevent control results from being stored in the internal memory as patient results. 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 when the measurements are performed in the "control solution mode". An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. Hematocrit Study: To evaluate the effect of hematocrit on the Prodigy Astro Blood Glucose Monitoring System, venous blood samples were adjusted to hematocrit levels of 15 %, 20 %, 30 %, 42 %, 60 % and 65 %. Each hematocrit level was tested at five glucose concentration intervals (30-50, 51-110, 111-150, 151-250, 251-400 mg/dL) for a total of 30 samples. Results from the meter were compared to results obtained using a laboratory-based reference measurement (YSI 2300 analyzer). The evaluation of percent bias relative to values obtained on the YSI 2300 analyzer demonstrated acceptable performance across the claimed hematocrit range of 20-60%.
2. Altitude study: To evaluate the effect of altitude on the Prodigy Astro Blood Glucose Monitoring System, meters were tested at six altitudes above sea level (298 ft; 2,920 ft; 4,790 ft; 6,234 ft; 8,563ft and 11,161 ft). Five glucose levels (43.5, 82.0, 130, 198, and 316 mg/dL) were tested at each altitude. The evaluation included testing each sample with three strip lots and three sets of meters. Each lot included 10 replicates for a total of 30 replicates per glucose level/altitude combination. Results were compared to results obtained using a laboratory-based reference measurement (YSI 2300 analyzer) and demonstrated that altitudes up to 11,000 feet above sea level have no significant effect on blood glucose measurements.
3. Sample Volume: To verify the minimum sample volume requirement, venous whole blood samples with volumes ranging from 0.5 -1.5 µL were tested. Sample concentrations included five glucose levels (40.3, 76.6, 111.9, 176.6, and 340.7 mg/dL) tested at each volume. Testing included ten meters and ten strips from each of three lots for each glucose concentration/sample volume combination for a total of 30 measurements per volume/glucose level combination. Values obtained were compared to values obtained using a laboratory-based reference method (YSI 2300 analyzer). Results support a minimum sample volume of 0.7 µL for the Prodigy Astro/Prodigy Astro PRO blood glucose monitoring systems.

4. Temperature and humidity studies: To evaluate system performance under the extremes of the recommended temperature and humidity conditions, sample testing was performed at temperatures of 50, 77, and 104^{o}F, and R.H. of 10 and 85 %; each temperature was tested at both R.H. conditions using venous whole blood at glucose concentrations 49, 149, and 319 mg/dL. The evaluation included ten Prodigy Astro meters, and three strip lots with a total of 30 replicates per glucose level/environmental condition combination. The results obtained on the Prodigy Astro blood glucose monitoring system were compared to those obtained on the YSI 2300, and support the operating conditions of temperatures of 50 - 104^{o}F (10-40^{o}C) and RH of 10-85%.

5. Infection Control and Robustness Studies: The Prodigy Astro Blood Glucose Monitoring System is intended for single-patient use and the Prodigy Astro Pro Blood Glucose Monitoring System is intended for multiple-patient use in clinical settings. Disinfection efficacy testing on the surface materials of the meter demonstrated complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, PDI SUPER SANI-CLOTH germicidal disposable wipes (EPA Registration # 9480-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after: 1) 520 cleaning and disinfection cycles (a total of 1040 wipes) designed to simulate 3 years of single-patient use for the Prodigy Astro Blood Glucose Monitoring System, and 2) 10,950 cleaning and disinfection cycles (a total of 21,900 wipes) designed to simulate three years of multiple-patient device use for the Prodigy Astro Pro Blood Glucose Monitoring System. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the Prodigy Astro/Prodigy Astro Pro Blood Glucose Monitoring Systems were found to be compliant.

7. Flesch-Kincaid readability assessment was conducted on all labeling and demonstrated that the User Manuals for the Prodigy Astro and Prodigy Astro Pro BGMS are written at an 8th grade level or below.

8. The meter manual states that customer service is available (Mon-Fri, 9AM to 5PM EST) by calling 1-800-243-2636.

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.