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

A. 510(k) Number:

k142785

B. Purpose for Submission:

New device

C. Measurand:

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

D. Type of Test:

Quantitative, amperometric method, glucose oxidase

E. Applicant:

OK Biotech Co., Ltd.

F. Proprietary and Established Names:

PRODIGY iConnect 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:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   The PRODIGY iConnect 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 iConnect Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The PRODIGY iConnect 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 iConnect 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).

   PRODIGY No Coding Blood Glucose Test Strips are intended for use with the PRODIGY iConnect blood glucose meter to measure the concentration of blood glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh for self-testing at home. They are for testing outside the body (in vitro diagnostic use only). Do not use them for diagnosis of, or screening for diabetes or for testing on neonates. PRODIGY No Coding Blood Glucose Test Strips are used as an aid to monitor the effectiveness of diabetes control.

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.
   - For single-patient use only.
   - Alternative site testing (AST) should only be done during steady-state times (when glucose is not changing rapidly, for example after meals, exercise, or after taking insulin).
   - AST should not be used to calibrate continuous glucose monitors (CGMs).
   - AST should not be used for insulin dose calculations.

4. Special instrument requirements:

   PRODIGY iConnect Blood Glucose Meter

I. Device Description:

The PRODIGY iConnect Blood Glucose Monitoring System consists of the PRODIGY iConnect Blood Glucose Meter, PRODIGY No Coding Blood Glucose Test Strips and PRODIGY Control Solutions (2 Levels – Level 1 and Level 2). The PRODIGY iConnect Blood Glucose Monitoring System is marketed as a Meter kit with a carrying case, battery, Meter User Guide, Quick Reference Guide, Logbook, Warranty Card, PRODIGY Lancing Device, PRODIGY Lancets, PRODIGY No Coding Blood Glucose Test Strips, and PRODIGY Control Solution (Level 1). The system is also marketed as a Simple kit that includes all components of the Meter Kit except for PRODIGY No Coding Blood Glucose Test Strips and PRODIGY Control Solution. The test strips and control solutions are available separately.

The system has the ability to physically connect to mobile devices for the purpose of storing blood glucose measurements via a mobile App. When the PRODIGY iConnect meter is connected to a compatible phone, the App receives the test results and allows users to display, store, and track blood glucose measurement data. Users can also use the App to upload their blood glucose measurements to a Cloud account or email the data to others. For real-time measurements, the App can serve as an aid to the user in operating the meter, e.g. by displaying a prompt to insert a test strip into the meter and by counting down 6 seconds after a blood sample is applied. The App is specific to the PRODIGY iConnect Blood Gluose Monitoring System and cannot be used with other glucose meters. The App is compatible with iOS 6.0 and higher as well as the Android Jelly Bean and Android KitKat operating systems.

The PRODIGY iConnect blood glucose meter can function independently of the App and without connection to a mobile device.

The PRODIGY No Coding Blood Glucose Test Strips contain the following reagent composition: 0.4% glucose oxidase (Aspergillus Niger), 3.8% potassium ferricyanide (electron shuttle), and 95.8% non-active ingredients and enzyme protector. The test strips are available for purchase separately.

The PRODIGY Control Solutions Level 1 and Level 2 were previously cleared in k122338. Level 1 is included in one kit configuration (Meter kit) and both Level 1 and Level 2 are available for purchase separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   PRODIGY Preferred Blood Glucose Monitoring System

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

   K122338

3. Comparison with predicate:

Similarities/Differences		
Item	Candidate Device PRODIGY iConnect Blood Glucose Monitoring System	Predicate Device Prodigy Preferred Blood Glucose Monitoring System (k122338)
Indications for use	The device is intended for quantitative measurement of glucose in fresh capillary whole blood by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.	Same
Test strip used	PRODIGY No Coding Blood Glucose Test Strips	Same
Control solutions used	PRODIGY Control Solutions (Level 1, Level 2)	Same
Detection method	Amperometric method	Same
Enzyme	Glucose oxidase	Same
Specimen type	Capillary whole blood from fingertip, palm, forearm, upper arm, calf, and thigh	Same
Operating conditions	50 – 104°F (10 – 40°C), 10-85% R.H.	Same
HCT range	20 - 60%	Same
Detection range	20 – 600 mg/dL	Same
Measuring time	6 seconds	7 seconds
Meter size	48 mm (L) x 47 mm (W) x 13 mm (H)	71mm (L) x 60 mm (W) x 19 mm (H)
Meter weight	~ 20 g (with battery)	~ 45 g (with battery)
Power battery	One 3V CR2032 battery	Same
Memory storage	100 tests	120 tests
Mobile app connectivity	Yes	No
Glucose Value Averaging	No	Yes – 7, 14, 21 and 28 day averaging

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

CLSI EP5-A2 "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved guideline – Second Edition"

CLSI EP6-A "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline"

CLSI EP7-A2 "Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition"

IEC 60601-1-2 “Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests”

L. Test Principle:

Blood glucose is measured by an electrical current that is produced when a blood sample mixes with the reagents of the test strip. The electrical current changes with the amount of glucose in the blood sample. The meter measures the strength of the electrical current, calculates the blood glucose level and then displays the result in either milligrams of glucose per deciliter (mg/dL) or millimoles of glucose per liter (mmol/L).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-Run Precision
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 glucose level for each meter. Results are summarized below:

Glucose Level, mg/dL	Strip Lot	n	Meter Reading, mg/dL	SD, mg/dL	CV, %
30-50	1	100	39.4	2.8	7.2
	2	100	40.1	2.7	6.6
	3	100	39.9	2.6	6.6
	Combined			2.7	6.8
51-110	1	100	81.5	3.7	4.5
	2	100	81.5	4.0	4.9
	3	100	82.0	3.7	4.6
	Combined			3.8	4.7
111-150	1	100	129.5	4.9	3.8
	2	100	130.4	4.7	3.6
	3	100	129.6	4.7	3.6
	Combined			4.8	3.7
151-250	1	100	199.5	5.7	2.9
	2	100	198.7	6.1	3.1
	3	100	199.1	6.0	3.0
	Combined			6.0	3.0
251-400	1	100	328.6	8.3	2.5
	2	100	326.6	8.5	2.6
	3	100	326.2	8.0	2.5
	Combined			8.3	2.5

Intermediate Precision

Intermediate (between run) Precision was evaluated using 5 levels of glucose control solutions (30 to 50, 51 to 110, 111 to 144, 151 to 250, 280 to 400 mg/dL) over 10 days with 3 test strip lots. For each level, on each day, 10 meters were used for testing, with 1 replicate collected per meter for a total of 10 replicates per day for each glucose level. Results are summarized below:

Glucose Level, mg/dL	Strip Lot	n	Meter Reading, mg/dL	SD, mg/dL	CV, %
30-50	1	100	44.3	2.9	6.6
	2	100	44.9	3.1	7.0
	3	100	44.1	2.9	6.7
	Combined			3.0	6.8
51-110	1	100	80.1	3.3	4.1
	2	100	79.3	2.9	3.7
	3	100	79.8	3.3	4.1
	Combined			3.2	4.0
111-144	1	100	127.7	4.0	3.1
	2	100	128.1	3.7	2.9
	3	100	128.2	4.1	3.2
	Combined			4.0	3.1
151-250	1	100	200.1	5.4	2.7
	2	100	199.0	5.2	2.6
	3	100	200.5	5.4	2.7
	Combined			5.4	2.7
280-400	1	100	342.6	9.1	2.7
	2	100	341.4	8.5	2.5
	3	100	341.4	8.7	2.5
	Combined			8.8	2.6

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, 25, 95, 165, 235, 305, 375, 445, 515, 585, and 615.

Low samples were prepared by allowing glycolysis to occur. High samples were prepared by spiking into the venous whole blood samples. Values were confirmed using a laboratory reference method (YSI 2300 analyzer) calibrated with NIST reference material.

10 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	1.0001	-0.8111	0.9997
2	1.0036	-3.0874	0.9998
3	1.0026	-2.1376	0.9999
Combined	1.0002	-1.9588	0.9999

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

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

The system is traceable to NIST standard NISH SRM #917c Clinical Dextrose.

Test strip stability:

Stability protocols and acceptance criteria for the PRODIGY No Coding Blood Glucose Test Strips were evaluated and found to be acceptable to support closed-vial stability of 24 months at 39.2-104°F (10-85% relative humidity) and open-vial stability of 90 days when test strips are stored at the recommended storage temperature (39.2-104°F) and 10-85% relative humidity or until the expiration date printed on the label, whichever comes first.

Control Solution Value Assignment and Stability:

PRODIGY Control Solutions were previously cleared in K122338. When stored between 39 and 86°F, the PRODIGY Control Solutions are stable for 18 months when unopened, and 90 days after first opening.

d. Detection limit:

The reportable range is 20 to 600 mg/dL and is supported by results of the linearity study described above (M.1.b).

e. Analytical specificity:

Interference studies were performed by spiking endogenous and exogenous potentially interfereing substances into venous whole blood. Each potential interferent was tested at 3 glucose levels (60, 120, and 250 mg/dL). Ten replicates were measured for each test sample. Results of test samples measured with the PRODIGY iConnect Blood Glucose Monitoring 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 using 3 test strip lots. Significant interference was defined by the sponsor as a bias $\geq \pm 10$ % of the test samples relative to control samples.

The sponsor claims no significant interference for the substances and concentrations shown in the table below:

Substance	Highest Concentration tested with no significant interference
Acetaminophen	8.0 mg/dL
Ascorbic acid	5.0 mg/dL
Aspirin	60 mg/dL
Bilirubin (unconjugated)	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
Hemoglobin	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	100 mg/dL
Tolbutamide	400 mg/dL
Triglyceride	2000 mg/dL
Uric acid	8.0 mg/dL
Xylose	100 mg/dL

The following information has been added to the labeling for this device based on results of the interference studies:

> The system exhibits interference from acetaminophen. Do not use during treatment with medications containing acetaminophen (e.g., Tylenol).
>
> Uric acid and ascorbic acid (when occurring in normal blood or taken at normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations of these substances in the blood may cause inaccurately high results. For example, if you are ingesting high levels of Vitamin C (ascorbic acid) you may get inaccurate results. If you have a disease or condition in which uric acid levels in your blood may be elevated, such as gout, you may also get inaccurate results with this system.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

See section M.3.c below for assessment of clinical performance.

b. Matrix comparison:

Not applicable

3. Clinicalstudies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

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

To assess the performance of the PRODIGY iConnect Blood Glucose Monitoring System in the hands of the intended users, the sponsor performed a study with 350 lay user participants who collected and tested samples from their own fingertip, palm, forearm, upper arm, calf and thigh. Results were analyzed by comparing capillary whole blood glucose results obtained by lay users with the PRODIGY iConnect Blood Glucose Monitoring System against results obtained with venous blood samples from the same patients analyzed by a laboratory reference method (YSI 2300 analyzer). The glucose concentrations in the samples ranged from 58.8 to 336.2 mg/dL as measured by the laboratory reference method. Results are summarized in the tables below:

For glucose concentrations <75 mg/dL

Sample Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	18/32 (56.3%)	31/32 (96.9%)	32/32 (100%)
Palm	16/32 (50.0%)	30/32 (93.8%)	32/32 (100%)
Forearm	21/32 (65.6%)	31/32 (96.9%)	32/32 (100%)
Upper arm	24/32 (75.0%)	32/32 (100%)	32/32 (100%)
Calf	18/32 (56.3%)	31/32 (96.9%)	32/32 (100%)

Thigh	15/32 (46.9%)	31/32 (96.9%)	32/32 (100%)

For glucose concentrations >75 mg/dL

Sample Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Finger	150/318 (47.2%)	251/318 (78.9%)	310/318 (97.5%)	318/318 (100%)
Palm	158/318 (49.7%)	262/318 (82.4%)	309/318 (97.2%)	318/318 (100%)
Forearm	160/318 (50.3%)	256/318 (80.5%)	311/318 (97.8%)	318/318 (100%)
Upper arm	137/318 (43.1%)	247/318 (77.7%)	302/318 (95.0%)	318/318 (100%)
Calf	159/318 (50.0%)	257/318 (80.8%)	312/318 (98.1%)	318/318 (100%)
Thigh	131/318 (41.2%)	241/318 (75.8%)	305/318 (95.9%)	318/318 (100%)

Linear regression analysis:

Sample Site	Slope	Intercept	R^2
Fingertip	1.0156	-2.5737	0.9689
Palm	1.0128	-1.3703	0.9724
Forearm	1.0125	-1.0703	0.9706
Upper arm	1.0017	-0.0689	0.9637
Calf	1.0075	-1.4061	0.9699
Thigh	1.0122	-0.7028	0.9658

A usability study was performed to assess the usability of the labeling. 350 lay user subjects were provided with the labeling in English. Subjects completed questionnaires regarding ease of use on a scale of 1(disagree) to 5 (fully agree) as well as specific questions to test understanding of information in the user manual. More than 85% of subjects agreed that the labeling, including the packaging and the user manual were easy to read.

4. Clinical cut-off**:**

   N/A

5. Expected values/Reference range:

   The following information is provided in the labeling:

"The normal adult fasting blood glucose range for a nondiabetic person is less than 100 mg/dL and less than 140 mg/dL up to 2 hours after meals."

Source: American Diabetes Association, September 22, 2014. http://www.diabetes.org/diabetes-basics/diagnosis.

N. Instrument Name:

PRODIGY iConnect Blood Glucose Meter.

O. System Descriptions:

1. Modes of Operation:

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

5. Calibration:

   This is a no-coding device and calibration is automatic. There is no user input for calibration.

6. Quality Control:

   Control materials comprise the two control solution levels which available for use with the device. PRODIGY Control Solution Level 1 is included with one kit configuration and both Level 1 and Level 2 are available separately for use with this system. 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 solution level is printed on the test strip vial label. The user is cautioned not to use the meter if results of control solution testing fall outside of 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 iConnect Blood Glucose Monitoring System, venous blood samples were adjusted to hematocrit levels of 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, and 60%. Each hematocrit level was tested at 5 glucose concentration intervals (30 to 50, 51 to 90, 120 to 150, 151 to 250, and 280 to 350 mg/dL) for a total of 30 samples. The evaluation included 10 meters, each tested with 3 lots of test strips. 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 hematocrit range of 20-60%.

2. Altitude study: To evaluate the effect of altitude on the PRODIGY iConnect Blood Glucose Monitoring System, meters were tested at 3 altitudes above sea level (2,920 ft; 6,234 ft; and 11,161 ft). Venous whole blood samples altered to 5 glucose levels (30 to 50, 51 to 110, 111 to 150, 151 to 250, and 251 to 400 mg/dL) were tested at each altitude. The evaluation included 3 meters and 3 test strip lots. Each test strip 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 11,161 feet above sea level have no significant effect on blood glucose measurements from the PRODIGY iConnect Blood Glucose Monitoring System.

3. Sample Volume: To demonstrate the minimum sample volume, venous whole blood samples with volumes ranging from 0.2 -1.5 µL were tested. Sample concentrations included 5 glucose levels (30 to 50, 51 to 110, 111 to 150, 151 to 250, 251 to 400 mg/d) at each sample volume. Testing included 10 strips from each of 3 lots for each glucose concentration/sample volume combination for a total of 30 replicates per volume/glucose level combination. 10 meters were used during testing. 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. The device produces an error message ("Lb") when the blood sample is ≤ 0.6µL.

4. Operating Conditions Study: Temperature and humidity operating conditions were using venous whole at 3 glucose concentration levels (38-68, 132-188, 280-420 mg/dL), 10 meters, and 3 lots of test strips. The following temperature and relative humidity (RH) conditions were tested: 50°F and 10% RH, 50°F and 85% RH, 104°F and 10% RH, 104°F and 85% RH. Individual glucose measurements were compared to an established laboratory reference method (YSI 2300 analyzer) and percent biases were calculated. Results support the claimed operating temperature range of 50°F to 104°F (10°C to 40°C) and relative humidity range of 10 to 85% RH.

5. Infection Control and Robustness Studies: The device is intended for single-patient use only. 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 3650 cleaning and disinfection cycles designed to simulate 5 years of device use with a maximum frequency of cleaning and disinfection 2x / day.

6. EMC Testing and Electrical Safety Studies: EMC testing was certified and appropriate compliance certificates were provided.

7. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (meter user guide, App user guide, test strip package insert, control solution package insert) were written at grade levels ranging from 6^{th} to 8^{th} grade.

8. The meter user guide states that technical support is available Monday through Friday, 9AM to 5 PM EST by calling1-800-243-2636.

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.