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

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

k090609

**B. Purpose for Submission:**

New device

**C. Measurand:**

Capillary whole blood glucose

**D. Type of Test:**

Quantitative, amperometric assay, glucose oxidase

**E. Applicant:**

OK Biotech, Co., Ltd.

**F. Proprietary and Established Names:**

OKmeter Match Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:
   21 CFR 862.1345, Glucose test system
   21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:
   Class II, Class I (reserved)

3. Product code:
   NBW, System, Test, Blood Glucose, Over The Counter
   CGA, Glucose Oxidase, Glucose
   JJX, Quality Control Material

4. Panel:
   Clinical Chemistry (75)

**H. Intended Use:**

1. Intended use(s):
   See Indications for Use below.

2. Indications(s) for use:
   The OKmeter Match Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program.

   It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative site testing in this system can be used only during steady-state blood glucose conditions. The meter has some audible features but it is not for use by the visually impaired.

3. Special conditions for use statement(s):
   - Over the Counter and professional use
   - Not intended for use on neonates
   - Not for the diagnosis of or screening for diabetes mellitus
   - Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill or in a hyperosmolar state
   - Allows testing on the fingertip, palm, forearm, upper arm, calf, or thigh
   - Alternative site testing can be used only during steady-state blood glucose conditions

4. Special instrument requirements:
   The Okmeter Match Meter

## I. Device Description:

The OKmeter Match Blood Glucose Monitoring System consists of the OKmeter Match meter, OKmeter Match test strips, clear cap for AST testing, a lancing device, lancets, user's manual, and quick reference guide. One level of OKmeter Control Solution (Normal) is provided with the kit and an additional level (High) is available for purchase.

The meter is sold with either Test Strip A or B. The only difference in these strips is the color. Strip A is white and strip B is green. The sponsor states that the use of the two colors helps track and manage the distribution of the strips.

## 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:

| **Similarities** | | |
|---|---|---|
| Item | Device | Predicate (k073118) |
| Indications for use | The OKmeter Match Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.<br>The alternative site testing in this system can be used only during steady-state blood glucose conditions. The meter has some audible features but it is not for use by the visually impaired. | Same |
| Test Principle | Electrochemical biosensor with carbon electrodes that measures current produced by a chemical reaction | Same |
| Enzyme | Glucose oxidase | Same |
| Sample Type | Fresh capillary whole blood | Same |
| Sample volume | 0.7 μL | Same |
| Sample Site | Fingertip, the palm, the forearm, the upper-arm, the calf and the thigh | Same |
| Memory feature | 450 measurement results with date and time | Same |
| Day average | 7-, 14-, 21-,28-, 60-, and 90- day average glucose result | Same |
| Speaking function | yes | yes |

| **Differences** | | |
|---|---|---|
| Item | Device | Predicate (k073118) |
| Measuring time | 6 sec | 7 sec |
| Measurement range | 25-580 mg/dL | 20-600 mg/dL |
| Meter dimensions (mm) | 4.13”(L)x2.17”(W)x0.71”(H) [105(L)x55(W)x18(H) mm] | 95(L)x55(W)x18(H) mm |
| Weight (g) | 82 g | 75 g |
| Test strip | OKmeter Match blood glucose test strip A (white) or B (green) | Prodigy Test Strip |

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

- CLSI EP5-A: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.
- ISO15197:2003- *In vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- ISO 5725-1:1994 Accuracy (trueness and precision) of measurement methods and results – Part 1: General principles and definitions.
- CLSI EP-6A: 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.
- EN 13640:2002, Stability testing of in vitro diagnostic medical devices.
- FCC 47 CFR, Part 18, 2004.
- IEC/EN 60601-1: Medical electrical equipment Part 1. General requirements for safety, 1988.
- IEC/EN 60601-1: Medical electrical equipment Part 1. General requirements for safety, 2001.
- IEC 61010-2-101: Safety particular requirements for IVD medical equipment, 2002.
- EC/EN 60601-1-2: Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests, 2001.

**L. Test Principle:**

The test is based on electrochemical biosensor technology and the principle of capillary action. The electrical current generated by the reaction of glucose with the reagent of the strip is measured by the meter and is displayed as the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:
   *a. Precision/Reproducibility:*

   Within-run and between-run precision studies were performed according to the CLSI EP5-A: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition, guideline.

   For the within-run precision studies 10 replicates of each of 5 spiked venous whole blood glucose levels (hematocrit of 35 to 50%) and 2 levels of control solutions (Normal and High), were analyzed using 10 meters, and three lots of each OKmeter Match blood glucose test strips (A and B). These tests were performed in one day, for a total of 100 test per each glucose level. Results are summarized below.

| | Strip A | | | | Strip B | | |
|---|---|---|---|---|---|---|---|
| **Samples** | Mean | SD | % CV | | Mean | SD | % CV |
| Interval 1<br>30-50 mg/dL | 33.4 | 2.9 | 8.6 | | 33.4 | 2.8 | 8.4 |
| Interval 2<br>51-110 mg/dL | 105.0 | 3.1 | 3.0 | | 105.0 | 3.2 | 3.7 |
| Interval 3<br>111-150 mg/dL | 142.1 | 4.3 | 3.0 | | 141.9 | 4.3 | 3.0 |
| Interval 4<br>151-250 mg/dL | 210.2 | 5.4 | 2.5 | | 209.9 | 5.6 | 2.6 |
| Interval 5<br>251-400 mg/dL | 349.4 | 10.8 | 3.1 | | 350.0 | 10.7 | 3.1 |
| Control<br>Normal<br>(100 mg/dL) | 100 | 3.2 | 3.2 | | 102.7 | 3.8 | 3.7 |
| Control<br>High<br>(300 mg/dL) | 295 | 5.6 | 1.9 | | 293.3 | 9.8 | 3.3 |

A precision study consisting of 60 replicates per day, per strip type for 10 days using 3 glucose control solutions, Low, Normal and High was conducted. Each sample was tested using the OKmeter Match blood glucose meter (10 meters), with OKmeter Match blood glucose test strips A and B (3 lots per strip), and the YSI 2300 glucose analyzer**.** Results are summarized below.

| | | Strip A | | | | Strip B | | |
|---|---|---|---|---|---|---|---|---|
| **Samples** | YSI | Mean | SD | %CV | | Mean | SD | %CV |
| Low<br>(30 to 50 mg/dL) | 47.3 | 45.4 | 2.8 | 6.2 | | 45.8 | 3.7 | 8.1 |
| Normal<br>(96 to 144 mg/dL) | 100.9 | 105.1 | 4.0 | 3.8 | | 105.6 | 3.9 | 3.7 |
| High<br>(280 to 420 mg/dL) | 286.8 | 270.3 | 10.3 | 3.8 | | 273.3 | 8.4 | 3.1 |

*b. Linearity/assay reportable range:*

Linearity was evaluated using 2 lots of each test strip (A and B), 5 OKmeter Match blood glucose meters, and 9 venous whole blood samples with glucose levels ranging from 24-581 mg/dL, obtained by spiking pooled venous blood with a dextrose solution. Each glucose level was analyzed 10 times for each test strip. Linear regression analysis for each test strip compared to the YSI resulted in:

$$y = 0.9910x + 4.9200;\ R^2 = 0.9992 \text{ for Test Strip A}$$

$y = 0.9908x + 3.9828$; $R^2 = 0.9991$ for Test Strip B

The claimed range of measurement for this device is 25 to 580 mg/dL.

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

The device showed traceability to a laboratory analyzer, YSI 2300 in the method comparison studies in 2.a. below.

Two levels of control material, OKmeter Control solution normal (100 mg/dL) and OKmeter Control solution high (300 mg/dL), are available for use with this test system. One level, the normal level, is provided with the meter. Shelf life and open vial stability were evaluated at 10-40ºC using 3 lots of each control solution. The results support the 18 month shelf life and the 90 day open vial stability claims.

Real-time stability studies demonstrated that the test strips, OKmeter Match test strips A and B, have a 24 month unopened shelf life and a 3 month shelf life once opened. The recommended storage temperature is 39 to 86°F (4 to 30°C) and below 85% humidity.

c. *Detection limit:*
The reportable range is 25 to 580 mg/dL based on linearity/reportable range studies above (section M.1.b.).

d. *Analytical specificity:*
The sponsor tested substances for interference using two test strips, A and B (3 lots of each), 10 meters, and 3 levels of glucose (achieved by adding 50-100, 200-275, and 400-500 mg/dL glucose to human venous blood). Samples were then spiked with the following interfering substances. Each sample was analyzed 20 times. The labeling states that elevated concentration of the following substances may affect test results. The following table lists the concentration of each substance at which no significant interference (≤ 10%) was detected:

| **Interfering Substance** | **Therapeutic/ Physiological Levels (mg/dL)** | **Test Range (mg/dL)** | **Acceptable Concentration (mg/dL)** |
|---|---|---|---|
| Uric Acid | 7 | 0-14 | ≤ 13 |
| Ascorbic Acid | 0.8-1.2 | 0-5 | ≤ 2.5 |
| Acetaminophen | 1-2 | 0-15 | ≤ 14 |
| Triglycerides | 190 | 0-2000 | ≤ 1500 |
| Dopamine | 0.4-1.6 | 0-10 | ≤ 5 |
| L-dopa | 0.02-0.3 | 0-1.5 | ≤ 1 |
| Methyldopa | 0.1-0.5 | 0-3 | ≤ 1 |
| Tolbutamide | 5.3-10 | 0-70 | ≤ 35 |
| Gentisic Acid | 3.5-5.0 | 0-10 | ≤ 8 |
| Hydroxyurea | <2 | 0-4 | ≤ 3 |

**Hematocrit study:**
The effect of different hematocrit levels was evaluated on the OKmeter Match blood glucose monitoring system with 3 lots of each test strip (A and B) using 20 samples at each of 6 concentration ranges of glucose (30, 85, 150, 300, 400, 500 mg/dL). The glucose samples were prepared from venous blood samples at 5 hematocrit levels at approximately 20, 30, 45, 50 and 55%. In total 100 measurements were made and each of the results compared to the value obtained from the same plasma glucose concentration obtained by YSI. The % bias did not exceed ±15 mg/dL for glucose values <75 mg/dL and did not exceed ±15% for glucose concentrations ≥75 mg/dL for hematocrit concentrations within the claimed range of 20 to 55%.

**Altitude study:**
Five whole blood samples with glucose concentrations ranging from 50 to 400 mg/dL were tested at 91, 890, 1460, 1900, 2610, 3402 meters (3402 meters ~ 11,161 feet). Each glucose concentration range was measured 6 times at each altitude. The bias was calculated relative to the results obtained at the local altitude (91 meters).

The results demonstrate that the system meets the accuracy acceptance criteria for testing at altitudes up to 3402 meters (11,161 feet) with biases less than ±15 mg/dL for samples ≤75 mg/dL, and less than 10% for samples containing >75 mg/dL glucose.

Temperature and humidity studies:
The sponsor performed temperature and humidity studies that demonstrated that the OKmeter Match system (with both strips A and B) can be used at temperatures of 50 to 104°F (10 to 40°C) and <85% relative humidity, and stored at temperatures of 39 to 86°F (4 to 30°C) and < 85% humidity.

*e. Assay cut-off:*
Not Applicable.

2. Comparison studies:
   *a. Method comparison with predicate device:*

**Reference Method Comparison:**
The sponsor performed a system accuracy evaluation comparing the OKmeter Match to YSI. Healthcare professionals tested 100 capillary samples in 5 concentration categories (<50, 50-80, 80-120, 120-200, 201-300, 301-400, and >400 mg/dL) per strip, using 2 meters and 3 lots of each test strip using the OKmeter Match and the YSI (the reference method). Results are summarized below.

**For glucose concentrations <75 mg/dL**

| **Test Strip A** | | |
|---|---|---|
| within ± 5 mg/dL | within ± 10 mg/dL | within ± 15 mg/dL |
| 13/18 (72.2%) | 17/18 (94.4%) | 18/18 (100%) |

| | | |
|---|---|---|
| **Test Strip B** | | |
| within ± 5 mg/dL | within ± 10 mg/dL | within ± 15 mg/dL |
| 14/18 (77.8%) | 18/18 100%) | 18/18 (100%) |

**For glucose concentrations ≥ 75 mg/dL**

| **Test Strip A** | | | |
|---|---|---|---|
| within ± 5 % | Within ± 10 % | within ± 15 % | within ± 20 % |
| 68/82 (82.9%) | 81/82 (98.8%) | 82/82 (100%) | 82/82 (100%) |
| | | | |
| **Test Strip B** | | | |
| within ± 5 % | within ± 10 % | within ± 15 % | within ± 20 % |
| 68/82 (82.9%) | 81/82 (98.8%) | 82/82 (100%) | 82/82 (100%) |

Linear Regression Analysis:

| Comparison | Strip | N | Slope and y-intercept | $R^2$ |
|---|---|---|---|---|
| OKmeter vs. YSI | Strip A | 100 | Y = 1.006x+1.000 | 0.999 |
| OKmeter vs. YSI | Strip B | 100 | Y = 1.006x+1.000 | 0.999 |

Fingerstick and Alternate Site Testing Comparison Studies:

The sponsor performed a lay-user study where accuracy of the device was tested using 160 fingerstick samples obtained by the lay-user and 110 samples per each alternative site (the palm, the forearm, the upper arm, the calf and the thigh) obtained by the lay-user. Participants, who were able to read the User's Manual in English, were instructed to read the manual and perform testing on the finger and then the alternative sites. A technician drew venous blood for measurements on YSI. Results were obtained for each of the alternative sites using each of the strips (test strip A and B). Samples ranged from 60 to 450 mg/dL. Results are summarized below.

Results from OKmeter Match blood glucose test strip A:

**For glucose concentrations <75 mg/dL**

| **Sites** | **within ± 5 mg/dL** | **within ± 10 mg/dL** | **within ± 15 mg/dL** |
|---|---|---|---|
| Finger | 4/10 (40%) | 8/10 (80%) | 10/10 (100%) |
| Palm | 4/12 (33.3%) | 8/12 (66.7%) | 12/12 (100%) |
| Forearm | 4/10 (40.0%) | 7/10 (70.0%) | 10/10 (100%) |
| Upperarm | 4/11 (36.4%) | 7/11 (63.6%) | 11/11 (100%) |
| Calf | 5/14 (35.7%) | 101/14 (71.4%) | 14/14 (100%) |
| Thigh | 4/10 (40.0%) | 7/10 (70.0%) | 10/10 (100%) |

**For glucose concentrations ≥75 mg/dL**

| **Site** | **Within ± 5 %** | **within ± 10 %** | **within ± 15 %** | **within ± 20 %** |
|---|---|---|---|---|
| Finger | 81/150 (54.0%) | 105/150 (70.0%) | 128/150 (85.3%) | 149/150 (99.3%) |
| Palm | 30/98 (30.6%) | 58/98 (59.2%) | 77/98 (78.6%) | 97/98 (99.0%) |
| Forearm | 41/100 (41.0%) | 69/100 (69.0%) | 84/100 (84.0%) | 98/100 (98.0%) |
| Upper arm | 34/99 (34.3%) | 68/99 (68.7%) | 80/99 (80.8%) | 98/99 (99.0%) |
| Calf | 35/96 (36.5%) | 69/96 (71.9%) | 80/96 (83.3%) | 94/96 (97.9%) |
| Thigh | 31/100 (31.0%) | 48/100 (48.0%) | 79/100 (79.0%) | 98/100 (98.0%) |

Linear Regression Analysis for Test Strip A:

| Comparison | Range (mg/dL) | N | Slope and y-intercept | $R^2$ |
|---|---|---|---|---|
| Finger vs. YSI | 61-449 | 160 | y=1.060x-4.531 | 0.961 |
| Palm vs. YSI | 64-449 | 110 | y=1.034x+4.559 | 0.956 |
| Forearm vs. YSI | 61-448 | 110 | y=1.073x-5.219 | 0.966 |
| Upperarm vs. YSI | 60-447 | 110 | y=1.050x-1.228 | 0.965 |
| Calf vs. YSI | 61-447 | 110 | y=1.037x+0.707 | 0.971 |
| Thigh vs. YSI | 63-447 | 110 | y=1.056x+0.866 | 0.965 |

Results from OKmeter Match blood glucose test strip B:

For glucose concentrations <75 mg/dL

| Site | within ± 5 mg/dL | within ± 10 mg/dL | within ± 15 mg/dL |
|---|---|---|---|
| Finger | 4/10 (40%) | 8/10 (80.0%) | 10/10 (100%) |
| Palm | 3/11 (27.3%) | 10/11 (90.9%) | 11/11 (100%) |
| Forearm | 3/11 (27.3%) | 9/11 (81.8%) | 11/11 (100%) |
| Upperarm | 4/11 (36.4%) | 6/11 (54.5%) | 11/11 (100%) |
| Calf | 3/11 (27.3%) | 6/11 (54.57%) | 11/11 (100%) |
| Thigh | 4/12 (33.3%) | 8/12 (66.7%) | 12/12 (100%) |

For glucose concentrations ≥75 mg/dL

| Site | Within ± 5 % | within ± 10 % | within ± 15 % | within ± 20 % |
|---|---|---|---|---|
| Finger | 55/150 (36.7%) | 108/150 (72.0%) | 126/150 (84.0%) | 149/150 (99.3%) |
| Palm | 35/99 (35.4%) | 63/99 (63.6%) | 80/99 (80.8%) | 98/99 (99.0%) |
| Forearm | 28/99 (28.3%) | 66/99 (66.7%) | 95/99 (96.0%) | 97/99 (98.0%) |

| | | | | |
|---|---|---|---|---|
| Upperarm | 34/99 (34.3%) | 62/99 (62.6%) | 81/99 (81.8%) | 97/99 (98.0%) |
| Calf | 28/99 (28.3%) | 60/99 (60.6%) | 81/99 (81.8%) | 96/99 (97.0%) |
| Thigh | 35/98 (35.7%) | 64/98 (65.3%) | 80/98 (81.6%) | 96/98 (98.0%) |

Linear Regression Analysis for Test Strip B:

| Comparison | Range (mg/dL) | N | Slope and y-intercept | $R^2$ |
|---|---|---|---|---|
| Finger vs. YSI | 61-448 | 160 | y=1.040x-0.659 | 0.957 |
| Palm vs. YSI | 60-445 | 110 | y=1.050x-1.336 | 0.960 |
| Forearm vs. YSI | 60-446 | 110 | y=1.072x-1.693 | 0.969 |
| Upperarm vs. YSI | 61-450 | 110 | y=1.025x+6.598 | 0.956 |
| Calf vs. YSI | 62-450 | 110 | y=1.066x-1.645 | 0.966 |
| Thigh vs. YSI | 62-442 | 110 | y=1.068x-1.536 | 0.971 |

*b. Matrix comparison:*
Not applicable. Capillary whole blood is the only indicated matrix.

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):*

4. Clinical cut-off:
   Not Applicable.

5. Expected values/Reference range:

| Time of day | Range, Non-diabetes |
|---|---|
| Fasting and before meals | Less than 110 mg/dL |
| 2 hours after meals | Less than 140 mg/dL |

The sponsor references: ADA Clinical Practice Recommendations 2003.

**N. Instrument Name:**
The OKmeter Match Meter

**O. System Description:**
1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for additional readings.

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 _____.

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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:
   This device is intended to be used with capillary whole blood from the finger, palm, forearm, calf, and thigh. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:
   The meter is a non-coding meter, therefore no coding is required by the user.

6. Quality Control:
   The sponsor provides one level of glucose control solution, normal, with this device. Two levels, normal and high, are available for purchase separately, as stated in the labeling. To perform a control test the user is instructed to press the "M" button while the blood drop symbol is flashing. The control bottle symbol will then appear on the display which means that the results will not be stored in memory. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, the user is referred to the user manual and customer support for problems and more information

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

The sponsor provided a readability study and obtained Flesch-Kincaid Grade Level Scores of 7.4 to 7.8 for the OKmeter Match User's Manual, test strip insert and control solution insert.

The sponsor stated that they conformed to the following guidelines and provided the appropriate documentation to demonstrate compliance:

- IEC/EN 60601-1: Medical electrical equipment Part 1. General requirements for safety, 1988.
- IEC/EN 60601-1: Medical electrical equipment Part 1. General requirements for safety, 2001.
- IEC 61010-2-101: Safety particular requirements for IVD medical equipment, 2002.
- EC/EN 60601-1-2: Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests, 2001.

**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.