

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

A. 510(k) Number:

k132633

B. Purpose for Submission:

New device

C. Measurand:

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

D. Type of Test:

Quantitative, amperometric method, Glucose Oxidase

E. Applicant:

OK Biotech Co., Ltd.

F. Proprietary and Established Names:

OKmeter Direct Blood Glucose Monitoring System

G. Regulatory Information:

Regulation Section	Classification	Product Code	Panel
21 CFR § 862.1345	Class II	CGA, glucose oxidase, glucose	Clinical Chemistry (75)
21 CFR § 862.1345	Class II	NBW, system, test, blood glucose, over the counter	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

OKmeter Direct Blood Glucose Monitoring System

The OKmeter Direct 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, calf, thigh, or palm. The OKmeter Direct Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The OKmeter Direct 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 OKmeter Direct 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 OKmeter Direct Test Strips are for use with the OKmeter Direct Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upperarm, calf, thigh, or palm.”

3. Special conditions for use statement(s):

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

4. Special instrument requirements:

OKmeter Direct Blood Glucose Meter

I. Device Description:

The OKmeter Direct Blood Glucose Monitoring System consists of the glucose meter, the Direct glucose test strips, lancing device, and the OKmeter Control Solutions (Level 1 and Level 2). The control solutions for use with the OKmeter Direct Blood Glucose Monitoring System were cleared under k090609. Test strips and one level of control material are included in the starter kit.

J. Substantial Equivalence Information:

1. Predicate device name(s):

OKmeter Match Blood Glucose Monitoring System

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

k090609

3. Comparison with predicate:

Similarities		
Item	Predicate Device OKmeter Match (k090609)	Candidate Device OKmeter Direct Blood Glucose Monitoring System
Intended Use	Quantitative measurement of glucose in fresh capillary whole blood to be used as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Test Principle	Electrochemical amperometric	Same
Enzyme	Glucose Oxidase	Same
Sample Type	Fresh Capillary Whole Blood	Same
Sample Volume	0.7 µl	Same
Sample Site	Fingertip, palm, forearm, upper arm, calf, thigh	Same
Measuring time	6 sec	Same

Differences		
Item	Predicate Device Okmeter Match (k090609)	Candidate Device OKmeter Direct Blood Glucose Monitoring System
Dimensions (length x width x height)	105 mm x 55 mm x 18 mm	95 mm x 45 mm x 18.35 mm
Weight (g)	82 g	70 g 83 g
Speaking Function	Yes	No
Memory Feature	450 measurements with date and time	180 measurements with date and time
Day Average	7, 14, 21, 28, 60, and 90 day	7, 14, 21, and 28 day
Measuring range	25-580 mg/dL	20-600 mg/dL
Hematocrit range	20-55%	20-60%
Humidity range	<85%	10-85%

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

- IEC/EN 60601-1: Medical electrical equipment Part I. General requirements for safety, 1995.
- IEC/EN 60601-1: Medical electrical equipment Part 1. General requirements for safety, 2001.
- IEC 61010-2-101: Safety particular requirements for IVD equipment, 2002.
- IEC/EN 60601-1-2: Medical electrical equipment, Part 2, Electromagnetic compatibility – Requirements and tests, 2007.
- FCC 47 CFR, Part 18, 2004.
- ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, 2003.
- CLSI EP5-A: Evaluation of Precision Performance of Quantitative Measurement 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. The glucose oxidase and potassium ferricyanide in the strip react with the glucose in the sample to produce an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Repeatability and between-run precision studies were performed using CLSI EP5-A: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.

The repeatability study was performed with venous whole blood samples at five glucose concentrations using three strip lots and ten meters. There were a total of twenty measurements per strip lot per glucose level per meter. These tests were performed in one day. Results are summarized below.

Test Strip Lot 1

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400
n	200	200	200	200	200
Mean (mg/dL)	46.4	92.0	134.0	239.0	329.3
Std Dev (mg/dL)	1.4	2.1	2.9	4.8	7.6
CV (%)	3.0	2.3	2.2	2.0	2.3

Test Strip Lot 2

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400
n	200	200	200	200	200
Mean (mg/dL)	46.1	92.1	133.7	239.4	328.8
Std Dev (mg/dL)	1.5	2.0	2.9	5.3	7.5
CV (%)	3.2	2.2	2.1	2.2	2.3

Test Strip Lot 3

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400
n	200	200	200	200	200
Mean (mg/dL)	46.4	91.9	134.1	239.3	329.7
Std Dev (mg/dL)	1.5	2.1	3.1	5.2	7.2
CV (%)	3.2	2.3	2.3	2.2	2.2

The between-run precision study was performed with glucose control materials at three levels. Each level was analyzed twenty times per day over ten days on each strip lot. Results are summarized below.

Test Strip Lot 1

Glucose conc.	Level 1	Level 2	Level 3
n	200	200	200
Mean (mg/dL)	51.0	99.1	292.0
Std Dev (mg/dL)	1.6	2.4	6.0
CV (%)	3.2	2.4	2.1

Test Strip Lot 2

Glucose conc. (mg/dL)	Level 1	Level 2	Level 3
n	200	200	200
Mean (mg/dL)	51.1	99.1	292.9
Std Dev (mg/dL)	1.7	2.3	6.1
CV (%)	3.2	2.3	2.1

Test Strip Lot 3

Glucose conc. (mg/dL)	Level 1	Level 2	Level 3
n	200	200	200
Mean (mg/dL)	51.1	98.8	294.0
Std Dev (mg/dL)	1.6	2.3	5.8
CV (%)	3.1	2.3	2.0

b. *Linearity/assay reportable range:*

Linearity was evaluated using two test strip lots and nine pools of venous blood samples with concentrations spanning the claimed measuring range (21, 51, 80, 149, 250, 349, 402, 497, and 604 mg/dL as measured by the reference method). Each level

was measured 10 times per test strip lot and the values from the OK Biotech BGMS were compared with those obtained from YSI-2300. The results from linear regression analysis are summarized below:

Test strip Lot 1:

$$y = 0.98x + 1.33; r = 0.9996$$

Test strip Lot 2:

$$y = 0.98x + 0.88; r = 0.9996$$

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

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

Traceability:

According to the sponsor, the OKmeter Blood Glucose Monitoring System (BGMS) is traceable to the YSI 2747 Glucose Standard (NIST SRM #917c Clinical Dextrose). A method comparison was performed using the candidate device and a glucose oxidase method (YSI 2300) as the reference method (see Section M.2.a.)

Test Strip Stability

Closed vial (shelf life)

Test strip shelf life stability was assessed in real time studies. Testing protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims shelf life stability of 24 months at the recommended storage temperatures of 4 – 40° C and 10-85% relative humidity.

Opened vial (in-use)

Test strip opened vial stability was assessed in real time studies. Testing protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims an opened vial stability of six months at the recommended storage temperatures of 4 – 40° C and 10-85% relative humidity.

Two control solutions (Level 1 and Level 2) are available for use with the Okmeter Direct Blood Glucose Monitoring System. Value assignment and stability for the control solutions were evaluated in k090609. The shelf life and opened vial stability established in k090609 at 10– 40°C were 18 months and 90 days, respectively.

d. Detection limit:

The measuring range of the device is 20 - 600 mg/dL. This range was validated by the linearity study (M.1.b).

e. Analytical specificity:

The sponsor tested substances for interference using three lots of test strips, five meters, and three glucose concentrations in the ranges of 50 – 100, 200 – 275, and 400 – 500 mg/dL.

Venous whole blood samples were spiked to toxic levels or ten times the highest recommended therapeutic or physiological level. Each test sample was then tested five times per strip lot for a total of 15 measurements per sample per interferent. The sponsor defined no significant interference as $\leq \pm 10\%$. According to this criterion no significant interference was seen at the following concentrations:

Interferent	Level Tested
Acetaminophen	15 mg/dL
Ascorbic Acid	5 mg/dL
Aspirin	60 mg/dL
Bilirubin	90 mg/dL
Cholesterol	500 mg/dL
Creatinine	5 mg/dL
Dopamine	2 mg/dL
Galactose	900 mg/dL
Gentisic Acid	5 mg/dL
Hydroxyurea	3 mg/dL
L-dopa	10 mg/dL
Maltose	900 mg/dL
Methyldopa	3 mg/dL
Tolbutamide	400 mg/dL
Triglyceride	2000 mg/dL
Uric acid	8 mg/dL

However, the sponsor stated in the labeling that elevated concentrations of reducing substances occurring in the blood naturally (uric acid) or from therapeutic treatments (ascorbic acid, acetaminophen) may affect test results.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Fingerstick and Alternate Site Testing Comparison Studies:

To assess the performance of the OKmeter Direct Blood Glucose Monitoring System in the intended use population the sponsor performed a study with 135 lay user participants. The health care professional collected capillary blood from each participant from each sampling site and analyzed it using an OKmeter Direct Blood Glucose Monitoring System. Performance was evaluated by comparing blood glucose results from the candidate BGMS obtained by the health care professional against the reference value (YSI). The glucose concentration of the samples ranged from 57.8 to 391 mg/dL as measured by the reference method. The results are summarized in the

tables below for three strip lots combined.

For glucose concentrations < 75 mg/dL			
Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	17/21 (81%)	21/21 (100%)	21/21 (100%)
Palm	14/21 (67%)	21/21 (100%)	21/21 (100%)
Forearm	14/21 (67%)	20/21 (95%)	21/21 (100%)
Upper arm	15/21 (71%)	20/21 (95%)	21/21 (100%)
Calf	16/21 (76%)	20/21 (95%)	21/21 (100%)
Thigh	14/21 (67%)	20/21 (95%)	21/21 (100%)

For glucose concentrations ≥ 75 mg/dL				
Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Finger	84/114 (74%)	100/114 (88%)	111/114 (97%)	114/114 (100%)
Palm	74/114 (68%)	99/114 (87%)	110/114 (96%)	114/114 (100%)
Forearm	67/114 (59%)	97/114 (85%)	109/114 (96%)	114/114 (100%)
Upper arm	69/114 (61%)	100/114 (88%)	109/114 (96%)	114/114 (100%)
Calf	67/114 (59%)	99/114 (87%)	109/114 (96%)	114/114 (100%)
Thigh	74/114 (65%)	97/114 (85%)	109/114 (96%)	114/114 (100%)

Linear Regression Analysis		
Site	Slope and y-intercept	r ²
Finger	$y = 1.0001x - 0.6033$	r ² = 0.9884
Palm	$y = 0.99x + 1.7572$	r ² = 0.9859
Forearm	$y = 0.9962x - 0.9202$	r ² = 0.9843
Upper arm	$y = 1.0111x - 1.2414$	r ² = 0.9808
Calf	$y = 0.967x + 3.9017$	r ² = 0.9823
Thigh	$y = 1.0095x - 1.1861$	r ² = 0.9856

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):*

Fingerstick and Alternate Site Testing Comparison Studies:

To assess the performance of the OKmeter Direct Blood Glucose Monitoring System in the intended use population the sponsor performed a study with 135 lay user participants who did not have any experience using an OKmeter Direct Blood Glucose Monitoring System. Training in this study consisted only of the participants reading the OKmeter Direct user guide written in English. For each sampling site, the participants collected and analyzed their own sample using the OKmeter Direct system. Performance was evaluated by comparing blood glucose results from the candidate BGMS obtained by the lay user against the reference value (YSI). The glucose concentration of the samples ranged from 57.8 to 391 mg/dL as measured by the reference method. The results are summarized in the tables below for three strip lots combined:

For glucose concentrations < 75 mg/dL			
Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	15/21 (71%)	21/21 (100%)	21/21 (100%)
Palm	15/21 (71%)	20/21 (95%)	21/21 (100%)
Forearm	15/21 (71%)	20/21 (95%)	21/21 (100%)
Upper arm	14/21 (67%)	20/21 (95%)	21/21 (100%)
Calf	14/21 (67%)	20/21 (95%)	21/21 (100%)
Thigh	18/21 (86%)	21/21 (100%)	21/21 (100%)

For glucose concentrations ≥ 75 mg/dL				
Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Finger	83/114 (73%)	100/114 (88%)	111/114 (97%)	114/114 (100%)
Palm	74/114 (65%)	102/114 (89%)	111/114 (97%)	114/114 (100%)
Forearm	64/114 (56%)	99/114 (87%)	113/114 (99%)	114/114 (100%)
Upper arm	75/114 (66%)	102/114 (89%)	111/114 (97%)	114/114 (100%)
Calf	66/114 (58%)	98/114 (86%)	112/114 (98%)	114/114 (100%)
Thigh	72/114 (63%)	96/114 (84%)	110/114 (96%)	114/114 (100%)

Linear Regression Analysis		
Site	Slope and y-intercept	r ²
Finger	y = 0.982 + 1.2484	r ² = 0.9866
Palm	y = 0.9972x - 0.4212	r ² = 0.9874
Forearm	y = 0.9778x + 1.6689	r ² = 0.9817
Upper arm	y = 1.0089x - 1.377	r ² = 0.9805
Calf	y = 0.9884x + 1.3662	r ² = 0.9794
Thigh	y = 1.0191x - 3.1886	r ² = 0.986

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Time of day	Range, Non-diabetes
Fasting and before meals	Less than 100 mg/ml
Two hours after meals	Less than 140 mg/dl

The sponsor references: Diabetes Care January 2013 vol. 36 no. Supplement 1 S4-S10

N. Instrument Name:

OKmeter Direct Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

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

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

Yes No

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

Yes No

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes 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 device is intended to be used with capillary whole blood samples drawn from the fingertips, forearm, upper-arm, calf, thigh, or palm. The whole blood sample is applied

directly to the test strip by capillary action.

5. Calibration:

There is no coding required for the meter by the user. The meter is plasma calibrated.

6. Quality Control:

Two levels of OKmeter Control Solution are available and one level is provided in the starter kit. 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 patients results. An acceptable range for each control level is printed on the 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

The effect of hematocrit levels was evaluated using venous whole blood samples with hematocrit levels of 15 – 65% (15, 20, 25, 30, 35, 40, 45, 50, 55, 60 and 65%) spiked with glucose to achieve target concentrations of 80, 125, and 320 mg/dL. Twenty measurements were obtained for each combination of glucose target concentration and hematocrit and compared to the value obtained from the YSI. The results demonstrated that the OKmeter Direct Blood Glucose Monitoring System produces accurate results over the claimed hematocrit range of 20 – 60%.

2. Sample Volume Study

The recommended minimum sample volume for the OKmeter Direct Blood Glucose Monitoring System is 0.7 µl. The sponsor performed a study to determine the effect of sample volumes from 0.5 to 1.5 µl in comparison to YSI. The study supports the sponsor’s claimed minimum sample volume of 0.7 µl.

3. Altitude Study

An altitude study was performed in venous whole blood using three meters and three lots of test strips at five glucose levels in the ranges of 30 – 50, 51 – 110, 111 – 150, 151 – 250, and 251 – 400 mg/dL. The meter results were compared to the reference YSI at various altitudes up to 10335 feet (3150 meters). The study supports the sponsor’s claimed maximum altitude of 10335 feet.

4. Temperature and Humidity Studies

To evaluate the effect of temperature and humidity the sponsor compared the meter results vs. the reference method under the following environmental conditions:

Temperature (° C)	Relative Humidity (%)
10	10
10	85

40	10
40	85
45	10
45	85

Three glucose concentrations (ranges 38 – 68, 132 – 188, and 280 – 420 mg/dL) were tested in venous whole blood at each combination of temperature and humidity above using three lots of strips. The study results support the claimed operating conditions of 10 – 40° C and 10 – 85% relative humidity.

5. Infection Control

The OKmeter Direct Blood Glucose Meter is intended for single-patient use only. Virucide efficacy testing was performed by an outside commercial testing service using Hepatitis B surface antigen (HBsAg) demonstrating disinfection efficacy with DISPATCH Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg No.56392-8) on the materials comprising the meter. The sponsor also conducted robustness studies and demonstrated that there was no change in the performance or the external materials for the meter after 520 cleaning and disinfection cycles to simulate 5 years of single-patient use by lay-users. Each robustness cycle consisted of one pre-clean wipe and one disinfecting wipe. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. Electromagnetic Compatibility

Electromagnetic compatibility (EMC) testing was performed on OKmeter Direct, Blood Glucose Meter. A signed technical compliance statement was provided to demonstrate that the EMC testing was performed according to the standards listed in the test report. The test report indicates that the OKmeter Direct Blood Glucose Meter is compliant with the requirements of the listed standards.

7. Readability Assessment

The strip labeling and User’s Manual returned a Flesch-Kincaid reading level of 7.8 and 7.5 respectively.

8. Customer Service

Customer Support is available Monday - Friday from 9 am – 5 pm EST. The toll free phone number is 1-800-243-2636. Users are instructed to contact their healthcare provider when customer support is not available.

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.