

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

A. 510(k) Number:

k063026

B. Purpose for Submission:

Clearance of a new device.

C. Measurand:

Glucose

D. Type of Test:

Blood Glucose Concentration through a Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:

OK Biotech Co., Ltd.

F. Proprietary and Established Names:

OK Meter Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Glucose Test System

21 CFR § 862.1660, Single (specified) analyte controls (assayed and unassayed)

2. Classification:

Class II

Class I (reserved)

3. Product code:

NBW, CGA, JJX

4. Panel:

75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):

See Indications for use.

2. Indication(s) for use:

The OK Meter Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger. Testing is done outside the body (in vitro diagnostic use). It is indicated for both lay uses by people with diabetes, and in a clinical setting by health care professionals, as an aid to monitoring levels in Diabetes Mellitus. Not for use on neonates.

3. Special conditions for use statement(s):

For Over-the-Counter use.

4. Special instrument requirements:

OK Meter Blood Glucose Monitoring System

I. Device Description:

The OK Meter Blood Glucose Monitoring System is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. The OK Meter Blood

Glucose Monitoring System uses a whole blood volume of 0.7 µL. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 6 seconds. The control solutions available are used to test the performance of the device.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Roche Diagnostics Corp. Accu-Chek Active Test System
2. Predicate 510(k) number(s):
k012324
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose Oxidase	Glucose Oxidase

Differences		
Item	Device	Predicate
Test Range	20 – 600 mg/dL	10 – 600 mg/dL
Volume Required	0.7 µL	1-2 µL
Hematocrit Range	20-60 mg/dL	20-70 mg/dL
Test Time	6 seconds	5 seconds

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

CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices
CLSI EP6-P: Evaluation of the Linearity of Quantitative Measurement Procedures

L. Test Principle:

Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

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

The sponsor evaluated the within run precision of the device using 20 replicate measurements of 5 concentrations of glucose-adjusted venous whole blood on 5 meters each tested with 3 strip lots. Results are summarized below.

Level	1	2	3	4	5
N	300	300	300	300	300
YSI	34	128	211	356	512
Mean	33.9	128.4	212.0	357.3	515.2
SD	3.89	6.6	9.5	11.3	20.2
%CV	11.5	5.1	4.5	3.2	3.9

The sponsor also evaluated the between run precision of the device using replicate measurements of glucose controls. Twenty replicates at 5 different concentrations (30-48, 104-148, 172-243, 293-386, 413-585) and 2 levels of controls (a low ~120 and high ~270) were each tested with 3 strip lots over 10 days. Results met the sponsor's acceptance criteria of a standard deviation ≤ 4.5 mg/dL when the glucose concentration was <75 mg/dL and less than a 6% CV for glucose concentrations ≥ 75 mg/dL.

b. Linearity/assay reportable range:

To establish the linearity of the OK Meter system through the range of 15 to 598 mg/dL glucose adjusted whole blood samples were compared to YSI 2300. Linear regression yields the following statistics:

N	20
Slope	0.991
y-intercept	5.54
r ²	0.9993

The sponsor claims 20 mg/dL as the lowest detectable limit in the labeling.

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

The device is traceable to a laboratory analyzer which is calibrated to a glucose standard (NIST SRM 965a). Stability characteristics of the two control solutions were determined using real-time stability studies to determine the storage stability at room temperature to be 18 months.

d. Detection limit:

The measuring range of the OK Meter Blood Glucose Monitoring System is 20 - 600 mg/dL. This range was verified by the linearity study (above).

e. Analytical specificity:

The sponsor tested the following substances for interference using two levels of glucose concentrations (~140 mg/dL and ~340 mg/dL). Interference was defined as $>15\%$ bias compared to YSI. The following results were determined with regard to interfering substances:

Substance	Therapeutic/Normal Concentration	Highest Concentration with $<15\%$ bias compared to YSI
Acetaminophen	1-2 mg/mL	15 mg/dL

Substance	Therapeutic/Normal Concentration	Highest Concentration with <15% bias compared to YSI
Dopamine	<87 pg/mL	300 mg/dL
L-Dopa	Not applicable	300 mg/dL
Tolbutamide	5.3-10 mg/dL	220 mg/dL
Ascorbic acid	0.8-1.2 mg/dL	5 mg/dL
Bilirubin	1.3 mg/dL	20 mg/dL
Galactose	Not applicable	10 mg/dL
Maltose	Not applicable	20 mg/dL
Triglyceride	36-165 mg/dL	300 mg/dL
Uric acid	7 mg/dL	13 mg/dL

An altitude study was performed with 7 whole blood samples ranging from 15-600 mg/dL. The spiked whole blood samples were measured by the OK Meter 6 times each. The samples were compared to YSI and found to have deviation less than 12 mg/dL for samples <70 mg/dL and less than a 6% CV for samples ≥ 70 . The sponsor claims that altitude up to 4691 feet has no effect on blood glucose measurements when using this test system.

To test the claimed hematocrit range, 20 replicates were tested at each hematocrit level and each glucose concentration. Samples were adjusted to hematocrit levels of 20%, 30%, 45%, 50%, and 65% and at glucose concentrations of 50, 80, 150, 300, 400, 500 mg/dL. Acceptable results were defined as 95% of samples falling into zone A of an error grid analysis and less than 5% falling into zone B compared when compared to a 45% hematocrit level. The performance was acceptable across the claimed hematocrit range of 20 – 60 %.

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

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor demonstrated that the OK Meter Blood Glucose Monitoring System for finger stick is equivalent to a standard method (YSI-2300) by having 150 patient samples with a hematocrit range of 35-55% test their own blood. A technician collected blood for YSI measurement and tested using the subject meter at the same time. Samples ranged from 71 to 414 mg/dL (according to YSI). The study results are summarized below:

	YSI vs. Patient Finger
N	150
Slope	0.9713
Intercept	2.707
r^2	0.9623

The sponsor also evaluated the results obtained by patients versus those obtained by

trained technicians. The sponsor found that differences between 150 samples obtained by both a patient and a technician were within $\pm 20\%$.

Meter versus YSI at each site met the ISO 15197 requirement of ninety-five percent (95 %) of the individual glucose results falling within ± 15 mg/dL of the results of the manufacturer's measurement procedure at glucose concentrations for samples <75 mg/dL and within $\pm 20\%$ at glucose concentrations ≥ 75 mg/dL. These results are summarized in the table below.

Site	Finger
N	150
Percentage That Met ISO Requirement	100% (150/150)

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):

The sponsor provided a readability study that indicated that the user manual, strip labeling, and control solutions are at a 7th grade reading level.

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

The sponsor included the following Expected Values for normal glucose levels in their strip labeling:

Status	Range (mg/dL)	Range (mmol/L)
Before breakfast	70-105	3.9-5.8
Before lunch or dinner	70-110	3.9-6.1
1 hour after meals	<160	<8.9
2 hours after meals	<120	<6.7
Between 2 and 4 AM	>70	>3.9

Source: Krall, L.P. and Beaser, R.S.: Joslin Diabetes Manual. Philadelphia: Lea and Febiger (1989), 138.

N. Instrument Name:

OK Meter Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

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

2. Software:

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

Yes ☒ 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:

This device is intended to be used with capillary whole blood from the finger only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A code number is provided with each batch of test strips to calibrate the meter for that batch. The code number must be entered into the meter to match the number found on the test strip vial. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing a single level glucose control solution with this device, though two levels are available for purchase as stated in the labeling. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is referred to a troubleshooting section of the owner's manual to identify possible reasons control results fall outside these ranges.

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

None.

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.