510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k062892

B. Purpose for Submission:

New device

C. Measurand:

Glucose

D. Type of Test:

Quantitative electrochemical biosensor

E. Applicant:

Eumed Biotechnology Co. Ltd.

F. Proprietary and Established Names:

EUKARE Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Number	Regulation Section	Panel
NBW	II	21 CFR 862.1345	Blood Glucose Test System-Over the-counter	75 Chemistry
CGA	II	21 CFR 862.1345	Glucose oxidase, glucose	75 Chemistry
JJX	I, reserved	21 CFR 862.1660	Single analyte controls	75 Chemistry

H. Intended Use:

1. Intended use(s):

   See indication for use statement below.

2. Indication(s) for use:

   The EUKARE Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by person with diabetes, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control.

   The measurement of glucose in whole blood can be taken from the finger only, and this is not for neonatal use.

   The EUKARE Blood Glucose Test Strips are intended to measure the glucose levels in whole blood with the EUKARE/EUSURE Blood Glucose Monitoring System. It is suitable for persons with diabetes to monitor their blood glucose levels at home by themselves. The system can also be used at clinical sites by health care professionals to test the blood glucose levels of patients.

   The EUKARE Blood Glucose Control Solution level I, level II, and level III are used as quality control material to verify the accuracy of the EUKARE/ EUSURE Blood Glucose Monitoring System. If you are not sure about the strip quality or the previous storage condition, you are recommended to perform a quality control check. The control test results should always fall within the designed range listed on the box in use.

3. Special conditions for use statement(s):

   The measurement of glucose in whole blood can be taken from the finger only, and this is not for neonatal use.

   The EUKARE Blood Glucose Control Solution for use with EUKARE/EUSURE Blood Glucose Monitoring System only.

4. Special instrument requirements:

   EUKARE/EUSURE Blood Glucose Monitoring System

I. Device Description:

The EUKARE/EUSURE Blood Glucose Monitoring System consists of the EUKARE Blood Glucose Test Strips, control solutions, and the EUKARE blood

glucose meter. The sample is drawn into a small chamber on the strip based on capillary action. It will fill the chamber automatically and stop when it reaches the end of the chamber, so sample volume control is achieved.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   EUSURE Blood Glucose Monitoring System

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

   k040678

3. Comparison with predicate:

Similarities		
Item	Subject Device EUKARE (Eumed) k062892	Predicate Device EUSURE (Eumed) k040678
Indications for Use	Intended for the quantitative measurement of glucose in fresh capillary whole blood.	Same
Test Principle	Electrochemical Biosensor with carbon electrodes	Same
Specimen	Capillary whole blood	Same
Sample Volume	~3 ul	Same
Measuring Time	15 sec	Same
Detecting Range	30-600 mg/dl	Same
Calibration method	Control solution	Same
Battery Power	One 3V Lithium	Same
Meter Check	Resistor (embedded in Check Code Card)	Same
Test Strip	EUKARE/EUSURE Glucose Test Strips	Same
Voltage	0.6V	Same
Button Design	2 in one button	Same
Meter Coding	Check Code Card	Same
Operating Temp.	10-40° C	Same
Strip Storage Temp.	4-30° C	Same

Differences		
Item	Device	Predicate
HCT Range	20-55 mg/dl	20-60 mg/dl

Differences		
Item	Device	Predicate
Meter Dimension	91 x 49x 21 mm	80 x 45 x 15 mm
Meter Weight	50 g	45 g
Meter Memory Storage	150 test results	100 test results

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

CLSI EP5-A Evaluation of Precision Performance of Clinical Chemistry Devices;
CLSI EP6-P2 Evaluation of the Linearity of Quantitative Analytical Methods;
CLSI EP7-A Interference testing in Clinical Chemistry;
CLSI EP9-A Method Comparison and Bias Estimation Using Patient Samples;
prEN 13640 Stability Testing of in vitro Diagnostic Medical Devices;
ISO 15197 In-vitro Diagnostic Test Systems-Requirements for Blood Glucose Monitoring Systems for Self-Testing;
IEC 61010 / EN 61010 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use;
IEC 60601 / EN 60601 Medical Electrical Equipment, General Requirements for Safety.

L. Test Principle:

The test principal is based on electrochemical biosensor technology using glucose oxidase. The strip uses the enzyme glucose oxidase to produce a current that will stimulate a chemical reaction with ferricyanide. This reaction is measured by the meter and displayed as a blood glucose result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were performed in the laboratory with EDTA venous whole blood. The blood glucose levels were adjusted to 5 different ranges by spiking the sample with glucose solution (20 g/dl). Precision studies were conducted with ten EUKARE meters and 500 EUKARE/EUSURE strips for ten duplicates to obtain the following results (n=100 per level). All of the tests were conducted within 30 minutes.

Concentration Range (mg/dl)	N	Total Mean (mg/dl)	Total SD (mg/dl)	Total CV%
30-50	100	39.61	2.66	6.68
51-110	100	81.88	3.24	3.96
111-150	100	124.98	2.91	2.33
151-250	100	161.51	5.71	3.53
251-400	100	310.85	9.74	3.13

b. *Linearity/assay reportable range:*

Linearity studies were conducted in accordance to CLSI guideline EP6-P. A venous whole blood sample was collected from a healthy person (HCT~ 42%). Half of the collected sample was adjusted to about 30 mg/dl with glucose stock solution. The other half of the collected sample was spiked to about 600 mg/dl with glucose stock solution. Three intermediate concentrations were prepared by combining the two spiked initial samples. All five samples were measured by a YSI glucose analyzer for verification. The linear regression equation for the linear regression analysis of results from the EUKARE device and the YSI method was Y= 0.9996x-0.2571, R^2=0.9995.

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

Control materials are traceable to YSI standards which are traceable to NIST SRM #965a (Glucose in frozen human serum: 4 glucose levels). Real-time shelf life studies performed by the manufacturer indicate that control solutions and the unopened test strips have a shelf life of 18 months. Once the control solution or strip containers are opened, they have been shown to be stable for 3 months.

d. *Detection limit:*

The measuring range is from 30 to 600 mg/dL (1.6 to 33.33 mmol/L). If the blood glucose value is below 30 mg/dl, “Lo” is displayed on the screen. If the blood glucose value is above 600 mg/dl, “Hi” is displayed on the screen. See precision and linearity studies above for validation of the measuring range.

e. *Analytical specificity:*

Interference testing was conducted to determine the effect of endogenous and exogenous substances according to CLSI EP7-P. According to this study, the sponsor determined that acetaminophen, ascorbic acid, dopamine, bilirubin and uric acid may lead to inaccurate glucose readings with the EUKARE/EUSURE blood glucose monitoring system to the extent shown below. The sponsor also determined the sodium fluoride should not be used be used with the EUKARE Blood Glucose Monitoring System.

Acetaminophen- will interfere with test results, each acetaminophen unit (mg/dl) will contribute about 3.86 mg/dL glucose for the EUKARE/EUSURE strip. The labeling contains a warning that patients taking acetaminophen should not use the meter.

Ascorbic Acid- levels lower than 1.5 mg/dl will not affect the glucose reading of the device. However, levels higher than 2 mg/dl will interfere with the EUKARE/EUSURE strip.

Dopamine-if a patient was treated with dopamine, the measurement results will be increased. The labeling contains a warning that patients taking dopamine should not use the meter.

Bilirubin- results up to 1.22 mg/dL do not interfere.

Uric Acid- concentrations higher than 7 mg/dL will have an effect on measurements of EUKARE/EUSURE Blood Glucose Monitoring System for the normal uric acid users.

Sodium Fluoride will interfere with the EUKARE Blood Glucose Monitoring System. This system is for fresh capillary whole blood only.

Altitude Effect

Six glucose devices, controls (4 levels) and strips (3 lots) were tested at 5 altitudes (up to 3000 meters). No effect on performance was found when the 4 control solutions were tested up to 9842 feet (3000 meters). Higher elevations were not tested.

Hematocrit Effect

The effect of hematocrit variation on the EUKARE Blood Glucose Monitoring System was tested by comparing results of different whole blood samples with hematocrit values ranging from 60% to 20% (increments of 10%). The samples were tested in replicates of four and the YSI 2300 Stat Plus served as the reference instrument. The sponsor used the ISO 15197 document system accuracy section to validate their high percent deviations from the average hematocrit (40%) values. The study supported a hematocrit range of 20 to 55%.

Temperature and Humidity Effect

The sponsor submitted data to support that the test system can be used between 56.3° -98.6° degrees Fahrenheit (12° and 37° C) and a relative humidity up to 93%.

f. Assay cut-off:

Not applicable

2. Comparison studies:

   a. *Method comparison with predicate device:*

      A clinical investigation was conducted to evaluate the system accuracy of the EUKARE meter. 146 volunteer samples (6 were excluded due to high hematocrit levels) consisting of 126 real samples and 20 spiked samples to obtain higher values were tested with the EUKARE meter, EUSURE meter and compared to YSI values. The samples ranged from 71 to 498 mg/dl and the hematocrit ranged from 34 to 55%. The agreement of the EUKARE capillary reading between the technician and lay user found that the lay user variability was less than +/- 20% of the technicians obtained values. The Error-Grid analysis to compare the capillary test result measured by EUKARE was plotted against the EUSURE reading obtained with the same volunteers' samples. 98% of all the data fell within the Zone A acceptance area. The device was compared to YSI values and yielded the following regression equation:

      $Y=1.0029x – 0.607$

      $R^2= 0.9941$

      N=146

      The sponsor also conducted a consumer questionnaire to investigate the consumers' ability to understand the use of the EUKARE Blood Glucose Monitoring System and strips. The results revealed a consumer average usability score of 96% and a consumer's ability to read and understand the insert had a score of 98%.

   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):

The sponsor's labeling was evaluated for readability via Flesh-Kincaid software and was given a 7.9 grade reading level score.

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

The sponsor quotes Tietz N.: Fundamentals of Clinical Chemistry 3rd Ed., W.B. Saunders Co., Philadelphia, PA, 1987, pg. 427.

Fasting Glucose:	90-130 mg/dl
Bedtime Glucose:	110-150 mg/dl

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.