

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k040678

B. Purpose For Submission:

Premarket Notification 510(k) of intention to manufacture and market the Eumed Biotechnology Co., LTD EUSURE Blood Glucose Monitoring System

C. Analyte:

Glucose

D. Type of Test:

Quantitative electrochemical biosensor

E. Applicant:

Eumed Biotechnology Co., Ltd.

F. Proprietary and Established Names:

EUSURE Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1345, Glucose test system
21 CFR §862.1660, Quality Control Material
2. Classification:
Class II
3. Product Code:
NBW, CGA, JJX
4. Panel:
75

H. Intended Use:

1. Intended use(s):

The EUSURE Blood Glucose Monitoring System is designed to measure the blood glucose levels in capillary whole blood. The system is suitable for diabetic patients 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 test range is from 30 mg/dL to 600 mg/dL (1.67 – 3.33 mmol/L).

2. Indication(s) for use:

The EUSURE Blood Glucose Monitoring System is designed to measure the blood glucose levels in capillary whole blood. The system is suitable for diabetic patients 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 test range is from 30 mg/dL to 600 mg/dL (1.67 – 3.33 mmol/L).

3. Special condition for use statement(s):

EUSURE Blood Glucose Test Strips and EUSURE Control Solution are to be used only with the EUSURE Blood Glucose meter to test glucose in finger stick capillary whole blood only. This meter is not to be used for Alternate Site Testing or Neonatal Testing.

4. Special instrument Requirements:

EUSURE Blood Glucose meter.

I. Device Description:

The EUSURE Blood Glucose Test Strips are used with the EUSURE blood glucose meter to quantitatively measure glucose in whole blood. 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 a good sample volume control is achieved. The EUSURE glucose test strip is a kind of electrochemical biosensor. The electron accumulates on the electrode when glucose reacts with the reagent on the electrode. A current can be detected by the EUSURE glucose meter when a constant voltage is applied across the electrodes. The current will be converted into glucose concentration by an embedded transfer function.

J. Substantial Equivalence Information:1. Predicate device name(s):

Apex Biotechnology Corp. GlucoSure Blood Glucose Monitoring System.

2. Predicate K number(s):

k002621

3. Comparison with Predicate:

The Eumed Biotechnology Co., LTD. EUSURE Blood Glucose Monitoring System is equivalent to the Apex Biotechnology Corp. GlucoSure Blood Glucose Monitoring System previously cleared under (k002621). The table below lists the similarities and differences between the Predicate and Proposed device.

Substantial Equivalence Comparison

Similarities

Item	EUSURE (Eumed) Subject Device (K040678)	GlucoSure (Apexbio) Predicate device (K002621)
Intended Use Intended Use (continued)	The EUSURE glucose test strip is intended to measure the glucose in whole blood with the EUSURE glucose meter. It is suitable for a person with diabetes to monitor their blood glucose at home by themselves. The system can also be used at clinical sites by nurses or professional people to test a patient's glucose level in whole blood.	The GlucoSure 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 persons with diabetes, or in clinical settings by health care professionals, as an aid to monitor the effectiveness of diabetes control.
Test Principle	Electrochemical biosensor with carbon electrodes	Same
Specimen Type	Capillary whole blood	Capillary whole blood
Sample Volume	Around 3 µL	
Measuring Time	15 seconds	15 seconds
Detecting Range	30 – 600 mg/dL	20 – 600 mg/dL
HCT Range	20 – 60 mg/dL	20 – 60 mg/dL
Calibration Method	Control Solution	Control Solution
Battery Power	One 3V Lithium CR 2032 battery	One 3V lithium coin cell battery
Meter Check	Resistor (embedded in Check Code Card)	Resistor (Check Strip)
EMC Test Standard	EN60601-1-2	EN60601-1-2

Differences

Item	EUSURE (Eumed) Subject Device (K040678)	GlucoSure (Apexbio) Predicate device (K002621)
Test Strip	EUSURE Glucose Test Strip	Sensorex / GlucoSure Test Strip
Meter Dimensions	80 mm X 45 mm X 15 mm	100 mm X 58mm X 21 mm
Meter Weight	45 g	64 g
Strip Dimension	6 mm X 35 mm X 0.6 mm	
LDC Display		
Applying Voltage	0.6 V	
Button Design	Two in one button	One button

Memory Storage	100 test results	10 blood glucose results
Data Recall	By button	None
Meter Coding	Check Code Card	Code Card
Operating Temperature	10 to 40° C	18 to 38° C

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

The EUSURE Blood Glucose Monitoring System conforms to the provisions of the EC directive IVDD (98/79/EC). The following standards apply to design and/ or manufacturing of the products:

Item	Standard
Quality System	ISO 13485
Risk Analysis	ISO 14971
Radiation Test	EN 60601-1-1-2 clause 36.201
Electromagnetic Compatibility	IEC 61326
Electrical Shock, Mechanical Hazard	IEC 61010- 1:2001
Performance (Precision, Accuracy, Repeatability Temperature Test)	ISO/DIN 15197
Linearity	NCCLS EP6-P
Interference	NCCLS EP7-P
Labeling	EN 376:2002(E), ISO 15223:2000
Lay Person	EN 376:2000(E)
Traceability	ISO 17511
Stability Test	prEN 13640

L. Test Principle:

The test principle is based upon electrochemical biosensor technology using glucose oxidase. The strip uses the enzyme glucose oxidase to produce a current that will stimulate a chemical reaction. This reaction is measured by the meter and displayed as your 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 four different ranges by spiking the sample with glucose solution. The measurement results of each sample were obtained by using 10 EUSURE glucose meters for 10 duplicates. All of the 100 test were completed within less than 30 minutes to avoid the glucose decaying problem.

Glucose Level	81 mg/dL	125 mg/dL	189 mg/dL	331 mg/dL
Number of Tests	100	100	100	100
Average (mg/dL)	99.27	140.49	215.88	377.02
S.D. (mg/dL)	5.64	6.54	9.12	20.78
C.V. (%)	5.68	4.65	4.22	5.51

Within Day Precision

Spiked whole blood samples at the below listed concentrations produced the following within day precision.

Concentration in mg/dL	n	Total mean	Total SD	Total CV%
30 – 50 mg/dL	100	45.1	3.10	6.90%
51 – 110 mg/dL	100	80.3	4.33	5.4%
111 – 150 mg/dL	100	129.1	6.50	5.0%
151 – 250 mg/dL	100	198.5	8.77	4.45
251 – 400 mg/dL	100	269.1	6.88	2.6%

b. Linearity/assay reportable range:

Linearity (analytical range) studies were designed in accordance with NCCLS Guideline EP6-A. The study protocol utilized a venous whole blood sample that was collected and allowed to stand overnight at room temperature. The glucose level was then measured on the YSI Glucose Analyzer. A 5 mL aliquot of the venous blood was transferred to another tube and the glucose level was adjusted to 30 mg/dL. Another 5 mL aliquot of this same patient sample was transferred to different tube, and the glucose level was adjusted to 600 mg/dL using a glucose stock solution (20 g/dL) in normal saline. Intermediate concentrations were made by a combination of the 30 mg/dL and 600 mg/dL samples. The recovered glucose values were plotted against the expected values with an appropriate line fitted by standard linear regression ($Y = 0.99X - 0.43$, $R^2 = 0.9887$). The EUSURE Blood Glucose Monitoring System shows a linear analytical range of 30 – 600 mg/dL. The sensitivity of the linearity claim is 0.99377 $\mu\text{A}/\text{mg}/\text{dL}$. NCCLS Proposed Guideline EP6-P. Evaluation of Linearity of Quantitative Analytical Methods was utilized to establish linearity.

c. Traceability (controls, calibrators, or method):

Traceability has been reference by the manufacturer to ISO 17511.

d. Detection limit:

The detection range is from 30 – 600 mg/dL (1.7 to 33.3 mmol/L).

e. Analytical specificity:

Interference testing was conducted to determine the effect of select endogenous and exogenous substances. According to this study, it has been determined that acetaminophen, ascorbic acid, dopamine, bilirubin and uric acid might interfere with the glucose measurement. (see below)

Acetaminophen - will interfere with test results, each acetaminophen unit (mg/dL) will contribute about 3.86 mg/dL glucose reading for the EUSURE strip.

Ascorbic acid -levels lower than 1.5 mg/dL have no effect, however, higher concentrations of ascorbic acid more than 2 mg/dL will interfere with the EUSURE strip.

Bilirubin - results up to 1.22 mg/dL have no effect. The hyper bilirubin is about 1.22 mg/dL for the clinical diagnostic criteria, the measurement results of EUSURE meter had no obvious drift in this concentration. Bilirubin has no clinical significance effect on measurement of EUSURE Blood Glucose Monitoring System for the normal bilirubin user.

Dopamine - patients treated with Dopamine, the measurement results will be higher.

Uric Acid- levels of 7 mg/dL have no obvious drift at this concentration, However, concentration greater than 7 mg/dL will have an effect on the measurement of the EUSURE Blood Glucose Monitoring System.

Sodium flouride - samples should not be used with the EUSURE Blood Glucose Monitoring System.

Interference studies were conducted according to NCCLS EP7-P.

f. Assay cut-off: NA

2. Comparison studies:

a. Method comparison with predicate device:

A clinical investigation had been conducted to evaluate the system accuracy of the EUSURE glucose monitor. 152 lay person volunteers' venous blood and plasma had been tested simultaneously by the EUSURE and Hitachi 7050 Clinical Analyzer respectively. The hexokinase reagent was used for the Hitachi auto-analyzer. The glucose levels of samples ranged from 66 to 430 mg/dL, and some high glucose samples were spiked with glucose stock solution. The hematocrit range of the samples was between 30 - 60% with an average hematocrit of 42%. The agreement of the EUSURE capillary reading between technician and lay

user found that the lay user variability was less than $\pm 20\%$ of the technician's values and 95% of the results were within 15% of each other. Using the Error-Grid analysis to compare the plasma glucose results to the capillary whole blood results, all values are within the A zone. The comparison yielded the following regression equation:

$$Y = 0.9771 X + 6.6618$$

$$R^2 = 0.9707$$

$$n = 152$$

b. Matrix comparison: NA

3. Clinical studies:

a. Clinical sensitivity: NA

b. Clinical specificity: NA

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

4. Clinical cut-off: NA

5. Expected values/Reference range:

The expected glucose value for a typical non-pregnant individual with diabetes is:¹

Fasting Glucose: 90 – 130 mg/dL

Bedtime Glucose: 110 – 150 mg/dL

¹ Tietz N.: Fundamentals of Clinical Chemistry 3rd Ed., W.B. Saunders Co., Philadelphia, PA, 1987 , p.427

Note: The above range is for reference, and it can not be suitable for every person. Consult your physician for the appropriate range for you.

N. Conclusion:

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