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

A. 510(k) Number:

k043340

B. Purpose for Submission:

The manufacturer submitted a 510(k) amendment to the EZ Smart Blood Glucose Monitoring System. This amendment addresses only labeling and indication changes for alternative site testing of the forearm. No physical changes were made to the originally cleared EZ Smart Blood Glucose Monitoring System (k040848)

C. Measurand:

Glucose

D. Type of Test:

Quantitative electrochemical biosensor technology

E. Applicant:

VIP International Wholesalers Corp.

F. Proprietary and Established Names:

EZ Smart Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1345, Glucose test system

2. Classification:

   Class II

3. Product code:

   NBW, CGA

4. Panel:

   75

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indication(s) for use:

   The EZ Smart Blood Glucose Test Strips are used with the EZ Smart Blood Glucose Meter to measure glucose (sugar) in whole blood. The EZ Smart Test Strips are for testing outside the body (in vitro diagnostic use). The EZ Smart Blood Glucose Monitoring System is intended for use in the home and in professional settings to monitor blood glucose levels for better glucose level control among diabetics.

   The EZ Smart Blood Glucose Monitoring System is indicated for use with capillary whole blood samples drawn from the fingertips and forearm.

3. Special conditions for use statement(s):

   EZ Smart Blood Glucose Test Strips and EZ Smart Control Solutions are to be used only with the EZ Smart Blood Glucose Meter to test glucose in fresh capillary whole blood only. This meter can be used for Alternate Site Testing of the forearm only. This meter is not to be used for Neonatal Testing

4. Special instrument requirements:

   EZ Smart Blood Glucose Meter.

I. Device Description:

The EZ Smart Blood Glucose Test Strips are used with the EZ Smart Blood Glucose Meter to quantitatively measure glucose in capillary whole blood. When the edge of the EZ Smart test strip is touched to a drop of blood, the test strip draws the blood into the sample chamber and the glucose reading is displayed on the meter after 10 seconds. The test measures glucose from 20 mg/dL (1.1mmol/L) to 600 mg/dL (33.3 mmol/L). The EZ Smart Test Strip is calibrated to display the equivalent of plasma glucose values to allow the comparison of results with laboratory methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   VIP Diagnostics EZ Smart Blood Glucose Monitoring System

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

   k040848

3. Comparison with predicate:

   The VIP Diagnostics LLC, EZ Smart Blood Glucose Monitoring System in this submission is the same VIP Diagnostics EZ Smart Blood Glucose Monitoring System previously cleared under (k040848). This submission was submitted to provide clinical studies of alternative site testing of the forearm by lay users.

Substantial Equivalence Comparison

Similarities

Item	Predicate Device EZ Smart (k040848)	Proposed Device EZ Smart (k043340)
Similarities	1. Monitors glucose using whole blood. 2. Directly displays results without requiring calculation. 3. Test principle includes measuring a current produced by a chemical reaction. 4. Test principle: Uses glucose oxidase reaction. 5. Measuring range: 20 to 600 ng/dL.	1. Monitors glucose using whole blood. 2. Directly displays results without requiring calculation. 3. Test principle includes measuring a current produced by a chemical reaction. 4. Test principle: Uses glucose oxidase reaction. 5. Measuring range: 20 to 600 mg/dL.

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

The EZ Smart Blood Glucose Monitoring System has been tested with the listed standards and found in compliance with the council EMC directive 89/336/EEC.

Test Standards		
EN 60601-1-2/1993	Medical electrical equipment – Electromagnetic compatibility	
	EN 55011/1998 + A1/1999	Emissions, Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and media (ISM) radio-frequency equipment.
	IEC 801-3/1984	Immunity, Electrostatic discharge
	IEC 801-3/1984 ENV 50204/1995	Immunity, Radio-frequency electromagnetic field.

CDRH documents: "Write it Right" and "Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care"

NCCLS Guideline GP-14P- Labeling for Home Use In Vitro Testing Products, NCCLS Guideline EP6-A, SMOG Readability Formula

L. Test Principle:

The test principle 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. This reaction is measured by the meter and displayed as the blood glucose result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

    a. *Precision/Reproducibility:*

    Within-run precision of EZ Smart test strips was measured with venous blood samples in the laboratory. The pooled precision data for three hundred seventy five test strip lots (n=375) is shown in the table below:

    Within-Run Precision

Average Glucose Concentration (mg/dL)	49.7	85	121	221	362
SD (mg/dL)	2.1	1.6	4.0	6.8	9.0
CV%	4.2	1.8	3.3	3.1	2.5

    b. *Linearity/assay reportable range:*

    Linearity (analytical range) studies were designed in accordance with NCCLS Guideline EP6-A. Venous blood was drawn from healthy

volunteers and collected into lithium heparin Vacutainer® tubes. The blood was then placed in a room temperature environment overnight, until glycolysis took place to reduce the glucose concentration to nearly zero. The blood was then pooled and allocated to lithium heparin tubes. A small amount of high concentration glucose (10,000 mg/dL) was added to each tube to obtain the desired blood glucose levels needed to perform the test.

Recovery tests were performed by confirming the blood glucose concentration with the YSI 2300. Blood samples with glucose concentrations ranging from 20 to 600 mg/dL were then tested with the EZ Smart Blood Glucose Monitoring System. Three lots of EZ Smart Test Strips, chosen at random, were used during the test. The test results were evaluated to describe accuracy over the entire range of blood glucose values. A linear regression analysis was performed by the method of least squares ($Y = 0.9717X + 3.66$, $R^2 = 0.9987$). The sensitivity of the system was determined by the slope of the regression line whereas the linearity was determined by the correlation coefficient of the regression line.

All measurements determined by the EZ Smart System are within a 15% bias of the reference (YSI 2300) results (glucose concentration > 100 mg/dL) and a 15 mg/dL bias of the reference (YSI 2300) results (glucose concentration < 100 mg/dL) see table below:

YSI (mg/dL)	20	75	152	258	359	482	600
EZ Smart Results Lot R030212	25	77	148	269	358	478	595
	23	82	139	258	354	459	589
	24	77	158	254	368	486	570
	20	71	156	245	348	469	591
	21	74	147	249	347	465	600
	28	76	155	243	345	462	597
	30	83	148	255	350	471	582
	26	76	155	248	351	467	591
MEAN	24.63	77.00	150.75	252.63	352.63	469.63	589.38
SD	3.38	3.93	6.36	8.37	7.44	8.78	9.55
CV%	13.72%	5.10%	4.22%	3.31%	2.11%	1.87%	1.62%
Bias%	23.13%	2.67%	-0.82%	-2.08%	-1.78%	-2.57%	-1.77%

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

Traceability has been referenced by the manufacturer to ISO 17511.

d. *Detection limit:*

The detection range is from 20 – 600 mg/dL (1.1 to 33.3 mmol/L). See linearity/assay detection limit above.

e. Analytical specificity:

Interference testing was conducted to determine the effect of selected endogenous and exogenous substances. The following study was used to elucidate whether the EZ Smart Blood Glucose Monitoring System is capable of a precise reading in blood samples containing the interferences. Interference studies were conducted according to NCCLS EP7-P.

The Interfering Effect of Drugs and Chemical Compounds on EZ Smart Test Strips.

Interfering Compounds	Physiological Levels Test Conc.	Test Concentration	No Interference Level of EZ Smart Test Strip
Acetone		6 mg/ml	6 mg/ml
Acetaminophen	20 µg/ml	40 µg/ml	30µg/ml
Ascorbic Acid	12 µg/ml	150 µg/ml	75 µg/ml
Alcohol		35 µg/ml	35 mg/ml
Barbital		1 mg/ml	1 mg/ml
Benzoic Acid		14.4 mg/ml	14.4 mg/ml
Bilirubin		200 µg/ml	200 µg/ml
Caffeine		1 mg/ml	1 mg/ml
Cholesterol	3 mg/ml	5 mg/ml	5 mg/ml
Cholic Acid		6 µg/ml	6 µmol/L
Creatinine	15 µg/ml	300 µg/ml	300 µg/ml
EDTA		4 mg/ml	4 mg/ml
Ephedrine	0.1 µg/ml	100 µg/ml	100µg/ml
Ethylene Glycol		40 µg/ml	40 mg/ml
Erythromycin		2 mg/ml	2 mg/ml
Glycerol		1 mmol/L	1 mmol/L
Ibuprofen	42 µg/ml	400 µg/ml	400µg/ml
L-DOPA	3 µg/ml	20 µg/ml	10 µg/ml
Lecithin		50 µg/ml	50 mg/ml
Potassium Chloride		10 µg/ml	10 mmol/L
Salicylate	0.3 mg/ml	1.25 mg/ml	1.25 mg/ml
Sodium Bicarbonate		40 mmol/L	30 mmol/L
Sodium Fluoride		5 mg/ml	3.75 mg/ml
Tetracycline	4 µg/ml	40 µg/ml	40 µg/ml
Tolazamide	25 µg/ml	50 µg/ml	37.5 mg/ml
Tolbutamide	0.1 mg/ml	1 mg/ml	1 mg/ml
Triglyceride	1.9 mg/ml	30 mg/ml	22.5 mg/ml

      f. Assay cut-off: Not applicable for this type of device.

2. Comparison studies:

    a. Method comparison with predicate device:

51 patients were tested for blood glucose levels using the EZ Smart Blood Glucose Meter and Strips. Blood glucose levels were determined from tests taken on the index fingers of each patient and compared to results from tests taken on their lower forearms.

A trained technician performed the comparison tests initially, followed by the patients on themselves. The technician tested an index finger on the right hand and the right lower forearm within a time limit of five minutes. The patient tested a finger on the left hand and the left lower forearm also within the five minute time limit. Comparative results were plotted on Clarke Error Grids and statistical analysis was performed to determine the correlation between the patient performed finger results to forearm results. The same comparison was calculated for the technician performed finger/forearm results. A comparison was also made between the technician performed test and the patient performed test.

The results of the statistical analysis of the Alternate site (Forearm vs. Finger stick) using EP Evaluator (3.23J) are tabulated below:

X / Y	Corr. Coeff. (R)	Slope Regular	Slope Deming	Intercept Regular	Intercept Deming
Tech Finger/ Tech Alternate	0.9925	1.006 (0.9716 – 1.041)	1.014 (0.9792 – 1.049)	-1.0 (-6.6 – 4.6)	-2.2 (-7.8 – 3.4)
Tech Alternate/ Patient Alternate	0.9810	0.9311 (.08798 - 0.9824)	0.9482 (0.8967 – 0.9997)	9.3 (0.9 - 17.6)	-2.2 (-7.8 – 3.4)
Tech Finger/ Patient Finger	0.9839	0.9146 (0.8683 – 0.9680)	0.9284 (0.8820 – 0.9748)	9.8 (2.3 – 17.3)	7.7 (0.2 – 15.2)
Patient Finger/ Patient Alternate	0.9862	1.021 (0.9731 – 1.069)	1.036 (0.9878 – 1.084)	-0.8 (-8.4 - 6.7)	-3.0 (-10.6- 4.5)

(95% Confidence Intervals are in parentheses).

The results of the Clarke Error Grid analysis are summarized below:

X / Y	Region	N	Percent	Cum Percent
Tech Finger/ Patient Alternate	A	51	100	100
Tech Alternate/ Patient Alternate	A B	49 2	96 4	96 100
Patient Finger/ Patient Alternate	A	51	100	100
Tech Finger/ Patient Finger	A B	49 2	96 4	96 100
Tech Finger/ Tech Alternate	A	51	100	100

    b. *Matrix comparison:*

       Not applicable for this type of device.

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 for this type of device

5. Expected values/Reference range:

    The normal fasting glucose range for a non-diabetic adult is 70 to 110 mg/dL. (3.9 to 6.1 mmol/L)[1]. One to two hours after meals, normal glucose values should be less than 120 mg/dL (6.7 mm0l/L)[2].

    1.   Burtis CA Ashwood ER, eds: Tietz Textbook of Clinical Chemistry. 2nd Edition. W.B. Saunders. Philadelphia. 1994. p. 2190.

2. Krall LP and Beaser RS: Joslin Diabetes Manual. Lea and Febiger. Philadelphia 1989. p. 138.

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.