

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

A. 510(k) Number:

k132406

B. Purpose for Submission:

Modification to existing device. The following changes have been made: smaller test strip, smaller strip connector and supplement strip holder, test strip cover, desiccant added to the test strip vial cap, test strip quantity in the vial, meter housing design, and addition of an insufficient sample volume alarm.

C. Measurand:

Capillary whole blood glucose from the finger, ventral palm, dorsal hand, upper arm, forearm, calf, and thigh

D. Type of Test:

Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:

Infopia Co., Ltd.

F. Proprietary and Established Names:

Element V Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NBW - Glucose test system	Class II	862.1345	Clinical Chemistry (75)
CGA – Glucose Oxidase, Glucose	Class II	862.1345	Clinical Chemistry (75)
JJX – Single (Specified) Quality Control Material (Assayed and Unassayed)	Class I (reserved)	862.1660	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See indications for use below
2. Indication(s) for use:

The Element™ V Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the finger, palm, hand, upper-arm, forearm, calf, and thigh. The Element™ V Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The Element™ V Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of or screening for diabetes and/or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The Element™ V test strips are for use with the Element™ V meter to quantitatively measure glucose (sugar) in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The Element™ V control solutions are for use with the Element™ V meter and the Element™ V test strips to check that the meter and test strips are working together properly and the test is performing correctly.

This meter contains some speaking functions but has not been validated for use by the visually impaired. By adding the voice function, users can hear test results, setting conditions and warning messages (errors) while performing the test. This added function is intended to aid users for their convenience.

3. Special conditions for use statement(s):

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

4. Special instrument requirements:
Element V Blood Glucose Meter

I. Device Description:

The proposed Element™ V Blood Glucose Monitoring System consists of a Element™ V Blood glucose meter, Element™ V test strips, Element™ V control solutions, Level 1, 2 and 3,, a reusable lancing device and lancets. The components will be marketed in the

following package options. The users can buy a system kit which includes all the components (meter, strips, 1 level of control solution, manual, log book, warranty card, quick reference guide, carrying bag, lancing device, and lancet), the meter package (meter, manual, warranty card) strip package (strips, manual, quick reference guide), control solution package (control solution, manual) and also, the meter, the strips and the control solutions can be purchased separately. The system can be used with GlucoDiary (k130181) a PC-based diabetes management system.

Element V glucose control solution was previously cleared under k130181, as GluNeo Control Solutions. There are 3 levels of controls with glucose concentrations of level 1 - 50 mg/dL, level 2 - 100 mg/dL, and 300 mg/dL. Control solutions contain known concentrations of glucose, stabilizers, buffers, preservatives and dyes.

Substantial Equivalence Information:

1. Predicate device name(s):
Element Plus Blood Glucose Test System
2. Predicate 510(k) number(s):
k103021
3. Comparison with predicate:

	Candidate Device	Predicate (k103021)
Type	Element V Blood Glucose Monitoring System	Element Plus Blood Glucose Monitoring System
Indications for Use/Intended Use	Intended for use in the quantitative measurement of glucose in fresh capillary whole blood by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program.	Same
Detection Method	Amperometry	Same
Sample Type	Capillary whole blood	Same
Sample Sites	Finger, palm, dorsal hand, forearm, upper-arm, calf, thigh	Same
Sample Volume	0.3 µL	Same
Measurement Range	20 - 600 mg/dL	Same
Test Strip	Auto-coding	Same
Speaking Function	Yes	Same
Reaction Time	3 sec	Same
Reagent Enzyme	Glucose Oxidase	Same

Altitude	10,000 feet above sea level	Same
Strip storage	36 - 86 °F	Same
Hematocrit Range (%)	20 - 60%	Same
Test strip dimensions	5 x 27 x 0.6 (mm)	6 x 33 x 0.6 (mm)
Meter dimensions	52 x 85 x 25 (mm)	54 x 82 x 24 (mm)
Control levels	3	Same

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

ISO 15197:2003: In Vitro Diagnostic Test Systems-Requirements for Blood Glucose Monitoring Systems for Self-Testing in Managing Diabetes

NCCLS EP9-A2 IR:2004, Method Comparison and Bias Estimation Using Patient Samples; Approved Guidelines – Second Addition

CLSI EP07-A2, Interference Testing in Clinical Chemistry, Approved Guideline – Second Edition

CLSI EP6-A:2005, Estimation of Linearity of Quantitative Measurement Procedures: A statistical approach; approved guideline

NCCLS EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition

EN 13640, Stability Testing of in vitro Diagnostic Reagents

ISO 14971:2007, Medical Devices – Application of risk management to medical devices

K. Test Principle:

The test is based on the measurement of electrical current generated by the reaction of capillary whole blood glucose with glucose oxidase of the test strip. The meter measures the strength of the current which is proportional to the concentration of glucose present and displays the corresponding blood glucose level.

L. Performance Characteristics (if/when applicable):

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

Repeatability (Within-run)

The sponsor performed within-run precision studies using venous whole blood samples adjusted to give the following five glucose concentrations (30 - 50, 51 - 110, 111 - 150, 151 - 250, and 251 – 400 mg/dL). Each glucose level was analyzed in replicates of 10, using three test strip lots, and 10 meters (N =300). The results are summarized below:

Lot 1	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL
YSI	40	79	130	207	340
Mean	43	77	133	209	333
SD	1.3	2.5	3.6	3.4	3.7
%CV	2.1	3.1	2.1	2.0	2.1
n	100	100	100	100	100

Lot 2	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL
YSI	40	79	130	207	340
Mean	42	75	134	208	339
SD	1.5	1.8	2.7	3.6	4.6
%CV	3.1	2.2	2.0	2.0	2.4
n	100	100	100	100	100

Lot 3	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL
YSI	40	79	130	207	340
Mean	45	79	132	205	340
SD	1.3	2.4	2.3	3.3	5.5
%CV	2.2	2.7	1.9	2.1	2.7
n	100	100	100	100	100

The combined within-run precision data for all three lots is described in the table below:

	Interval 1	Interval 2	Interval 3	Interval 4	Interval 5
[Conc.]	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL
Grand Mean (mg/dL)	44	78	133	206	338
Pooled SD (mg/dL)	1.8	2.7	2.9	3.6	5.3
Pooled %CV	2.5	2.6	2.4	2.1	2.6
n	300	300	300	300	300

Intermediate Precision (Between Run)

Between Run imprecision was evaluated by testing 3 levels of control solutions

using 3 test strip lots, 10 replicates per day for 20 days. The results are summarized below.

Lot 1	Level 1	Level 2	Level 3
Conc.	30 - 50	96 - 144	280 - 420
YSI	50	103	308
Mean	49	104	308
SD	1.4	3.4	4.2
%CV	2.1	3.1	1.3
n	200	200	200

Lot 2	Level 1	Level 2	Level 3
Conc.	30 - 50	96 - 144	280 - 420
YSI	50	103	308
Mean	48	105	308
SD	1.5	3.4	4.2
%CV	3.1	3.0	1.3
n	200	200	200

Lot 3	Level 1	Level 2	Level 3
Conc.	30 - 50	96 - 144	280 - 420
YSI	50	103	308
Mean	48	106	309
SD	1.2	3.3	4.3
%CV	2.4	3.0	1.3
n	200	200	200

The combined intermediate precision data for all three lots is described in the table below:

Control Level	1	2	3	n
[Conc.] mg/dL	50	103	308	
Grand Mean (mg/dL)	49	104	311	600
Pooled SD (mg/dL)	1.3	3.3	4.3	600
Pooled %CV	2.8	3.1	1.3	600

b. Linearity/assay reportable range:

Linearity was evaluated using 15 meters, three test strip lots and 14 glucose

venous blood samples ranging in glucose concentrations (as measured by YSI) of 19, 29, 48, 57, 69, 85, 95, 165, 235, 302, 387, 469, 543, and 606 mg/dL. Each level was measured in 5 replicates per lot for a total of 210 samples. Pooled and per lot data is below.

Lot	1	2	3
N	70	70	70
Slope	1.0461	0.9728	0.9807
y-intercept (mg/dL)	-4.6989	2.0376	1.5344
r ²	0.9993	0.9996	0.9996

Pooled	
N	210
Slope	0.9999
y-intercept (mg/dL)	-0.3757
r ²	0.9995

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

- c. *Traceability, Stability (21 CFR § 211.166), Expected values (controls, calibrators, or methods):*

Test Strip Stability:

The sponsor provided a real-time testing protocol and acceptance criteria to verify the closed- (shelf life) and open-vial stability of the test strips. The stability protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims a closed-vial (shelf life) of 24 months and open-vial stability of 6 months when stored at 35.6 – 86 °F and 20 - 60 percent relative humidity.

Traceability: The assay is traceable to NIST SRM 917b reference material.

Glucose control value assignment and stability: The glucose controls are the same as the controls in k130181, except in product name. Value assignment and stability were established in k051285. Unopened controls have a 24 month shelf life and are stable for 3 months after first use when stored at 46 – 86 °F.

- d. *Detection limit:*

See section M.1.b (linearity)

The reportable range is 20 to 600 mg/dL based on linearity/reportable range studies above. The low and high detection limits for this device have been set at 20 and 600 mg/dL. Readings below 20 mg/dL and above 600 mg/dL will indicate a “Lo” and “Hi” on the meter display, respectively.

e. *Analytical specificity:*

Interference

An interference study was performed to evaluate the effects of endogenous and exogenous substances on the glucose test results generated by the Element V Blood Glucose Monitoring System. Three glucose levels were achieved (53, 149, and 306 mg/dL) by collecting venous blood samples into tubes containing EDTA. Four levels of potential interferents were aliquotted into samples. The control pool (without an interfering compound) and 4 test pools were measured on five meters using one test strip lot. The bias was calculated by subtracting the mean control value from the interferent level mean value. The results are summarized below to show the highest concentration without significant interference (defined by the sponsor as ± 10 mg/dL < 75 mg/dL and $\pm 10\% \geq 75$ mg/dL).

Substance	Highest concentration without interference (mg/dL)
Acetaminophen	20
Ascorbic Acid	6
Bilirubin	40
Cholesterol	500
Creatinine	5
Dopamine	0.09
Galactose	50
Gentisic Acid	1.8
Glutathione	3
Ibuprofen	50
L-dopa	13
Maltose	300
Methyl dopa	1.5
Salicylic acid	60
Tolazamide	5
Tolbutamide	65
Triglycerides	3000
Uric Acid	23
Tetracycline	1.5
Urea	260
Ethanol	400
Hemoglobin	200
Warfarin	10
Xylose	200

-Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentration) do not significantly affect results. However, abnormally high concentration in blood may cause inaccurately high results

f. Assay cut-off:

- Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

System Accuracy

To assess system accuracy, results from the Element V Blood Glucose Monitoring System were compared to a reference method, YSI. Finger capillary samples collected by healthcare professionals from 100 participants with glucose concentrations ranging from 27 – 592 mg/dL (according to reference) were tested using three test strip lots. To obtain blood glucose concentrations <50 mg/dL and > 400 mg/dL, samples were allowed to glycolize or were spiked to achieve the desired glucose concentration. Ten samples were altered (5 glycolized, 5 spiked). The results relative to YSI are summarized in the tables below:

Finger

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
8/17 (47.1%)	16/17 (94.1%)	17/17 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
44/83 (53.0%)	75/83 (90.4%)	81/83 (97.6%)	83/83 (100%)
Accuracy of Element V (healthcare professional) compared to YSI using capillary whole blood (fingerstick)	n		100
	Slope (95% CI)		0.9998 (0.979 – 1.021)
	y-int. (mg/dL) (95% CI)		-2.6328 (-7.294 – 2.2028)
	r²		0.9890
	Range (mg/dL)		27 - 592

To assess system accuracy of alternative sites, results from the Element V Blood Glucose Monitoring System (alternative site) were compared to a reference method, YSI (finger). Dorsal hand, ventral palm, upper-arm, forearm, thigh and calf capillary samples were collected by healthcare professionals from 250 participants with glucose concentrations ranging from 65 – 400 mg/dL (according to reference) were tested using three test strip lots. The results relative to YSI are summarized in the tables below:

Dorsal Hand

For glucose concentrations < 75 mg/dL				
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL		
18/29 (62.1%)	29/29 (100%)	29/29 (100%)		
For glucose concentrations ≥ 75 mg/dL				
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %	
137/221 (62.0%)	198/221 (89.6%)	218/221 (98.6%)	221/221 (100%)	
Accuracy of Element V (healthcare professional) compared to YSI using capillary whole blood (Dorsal Hand)	n			250
	Slope (95% CI)			1.0035 (0.993 – 1.014)
	y-int. (mg/dL) (95% CI)			7.4735 (4.037 – 10.910)
	r²			0.9901
	Range (mg/dL)			67 – 400

Ventral Palm

For glucose concentrations < 75 mg/dL				
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL		
18/28 (64.3%)	28/28 (100%)	28/28 (100%)		
For glucose concentrations ≥ 75 mg/dL				
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %	
141/222 (63.5%)	194/222 (87.4%)	218/222 (98.2%)	222/222 (100%)	
Accuracy of Element V (healthcare professional) compared to YSI using capillary whole blood (Ventral Palm)	n			250
	Slope (95% CI)			1.0040 (0.993 – 1.015)
	y-int. (mg/dL) (95% CI)			5.6858 (2.625 – 8.747)
	r²			0.9929
	Range (mg/dL)			65 – 395

Upper-arm

For glucose concentrations < 75 mg/dL				
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL		
18/29 (62.1%)	29/29 (100%)	29/29 (100%)		
For glucose concentrations ≥ 75 mg/dL				
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %	
134/221 (60.6%)	188/221 (85.1%)	213/221 (96.4%)	221/221 (100%)	
Accuracy of Element V (healthcare professional) compared to YSI using capillary whole blood (Upper-arm)	n			250
	Slope (95% CI)			1.0050 (0.993 – 1.017)
	y-int. (mg/dL)			5.3194 (1.821 –

	(95% CI)	8.818)
	r²	0.9909
	Range (mg/dL)	70 – 400

Forearm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
19/29 (65.5%)	28/29 (96.6%)	29/29 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
142/221 (64.3%)	190/221 (86.0%)	216/221 (97.7%)	221/221 (100%)
Accuracy of Element V (healthcare professional) compared to YSI using capillary whole blood (Forearm)	n		250
	Slope (95% CI)		0.9998 (0.989 – 1.011)
	y-int. (mg/dL) (95% CI)		5.9269 (2.691 – 9.163)
	r²		0.9920
	Range (mg/dL)		65 – 398

Thigh

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
18/29 (62.1%)	28/29 (96.6%)	29/29 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
176/221 (79.6%)	206/221 (93.2%)	217/221 (98.2%)	221/221 (100%)
Accuracy of Element V (healthcare professional) compared to YSI using capillary whole blood (Thigh)	n		250
	Slope (95% CI)		0.9757 (0.965 – 0.987)
	y-int. (mg/dL) (95% CI)		4.1431 (1.014 – 7.272)
	r²		0.9921
	Range (mg/dL)		65 – 398

Calf

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
18/28 (64.3%)	28/28 (100%)	28/28 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
143/222 (64.4%)	194/222 (87.4%)	218/222 (98.2%)	222/222 (100%)
Accuracy of Element V (healthcare)			

professional)) compared to YSI using capillary whole blood (Calf)	n	250
	Slope (95% CI)	1.0055 (0.996 – 1.015)
	y-int. (mg/dL) (95% CI)	5.3809 (2.517 – 8.245)
	r²	0.9938
	Range (mg/dL)	68 – 388

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):

User Performance Study

To assess the performance of the Element V Blood Glucose Monitoring System in the hands of the lay-users, the sponsor performed a study with 231 lay-user participants, who collected 231 finger capillary samples using only English-written labeling materials with no other instructions or coaching. Results from two test strip lots and 6 meters were analyzed by comparing blood glucose results from the Element V meter obtained by the lay-user against the YSI reference value. The glucose concentration of the samples ranged from 57 to 417 mg/dL as measured by YSI. The results are summarized in the tables below:

Finger

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
29/40 (72.5%)	38/40 (95.0%)	39/40 (97.5%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
138/191 (72.3%)	186/191 (97.4%)	191/191 (100%)	191/191 (100%)
Accuracy of Element V (lay-user) compared to YSI using capillary whole blood (fingerstick)		n	231
		Slope (95% CI)	0.9969 (0.983 – 1.011)
		y-int. (mg/dL) (95% CI)	0.0258 (-3.713 – 3.764)
		r²	0.9889
		Range (mg/dL)	57 - 417

To assess system accuracy of alternative sites, results from the Element V Blood Glucose Monitoring System (alternative site) in the hands of lay-users the sponsor performed a study with 230 lay-user participants, who collected 230 capillary samples from the dorsal hand, ventral palm, upper-arm, forearm, thigh and calf using only English-written labeling materials with no other instructions or coaching. Glucose concentrations ranging from 65 – 400 mg/dL (according to reference) were tested using six test strip lots. The results relative to YSI are summarized in the tables below:

Dorsal Hand

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
20/29 (69%)	29/29 (100%)	29/29 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
123/201 (61.2%)	166/201 (82.6%)	193/201 (96%)	201/201 (100%)
Accuracy of Element V (lay-user) compared to YSI using capillary whole blood (Dorsal Hand)		n	230
		Slope (95% CI)	0.9988 (0.986 – 1.012)
		y-int. (mg/dL) (95% CI)	7.4735 (4.037 – 10.910)
		r²	0.9901
		Range (mg/dL)	67 – 400

Ventral Palm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
21/28 (75%)	26/28 (92.9%)	28/28 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
127/202 (62.9%)	174/202 (86.1%)	201/202 (99.5%)	202/202 (100%)
Accuracy of Element V (lay-user) compared to YSI using capillary whole blood (Ventral Palm)		n	230
		Slope (95% CI)	0.9855 (0.973 – 0.999)
		y-int. (mg/dL) (95% CI)	7.0391 (3.618 – 10.460)
		r²	0.9899
		Range (mg/dL)	65 – 395

Upper-arm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
22/29 (75.9%)	29/29 (100%)	29/29 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
124/201 (61.7%)	176/201 (87.6%)	193/201 (96.0%)	201/201 (100%)
Accuracy of Element V (lay-user) compared to YSI using capillary whole blood (Upper-arm)		n	230
		Slope (95% CI)	0.9961 (0.982 – 1.010)
		y-int. (mg/dL) (95% CI)	6.4301 (2.646 – 10.214)
		r²	0.9881
		Range (mg/dL)	70 – 400

Forearm

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
21/29 (72.4%)	26/29 (89.7%)	29/29 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
130/201 (64.7%)	173/201 (86.1%)	195/201 (97.0%)	201/201 (100%)
Accuracy of Element V (lay-user) compared to YSI using capillary whole blood (Forearm)			
		n	230
		Slope (95% CI)	0.9823 (0.969 – 0.995)
		y-int. (mg/dL) (95% CI)	7.1191 (3.696 – 10.542)
		r²	0.9898
		Range (mg/dL)	65 – 398

Thigh

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
22/29 (75.9%)	27/29 (93.1%)	29/29 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
137/201 (68.2%)	187/201 (93%)	197/201 (98.0%)	201/201 (100%)
Accuracy of Element V (lay-user) compared to YSI using capillary whole blood (Thigh)			
		n	230
		Slope (95% CI)	1.0254 (1.012 – 1.039)
		y-int. (mg/dL) (95% CI)	1.5731 (-5.212 – 2.066)
		r²	0.9894
		Range (mg/dL)	65 – 398

Calf

For glucose concentrations < 75 mg/dL			
within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL	
21/28 (75.0%)	26/28 (92.9%)	28/28 (100%)	
For glucose concentrations ≥ 75 mg/dL			
within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
127/202 (62.9%)	174/202 (86.1%)	201/202 (99.5%)	202/202 (100%)
Accuracy of Element V (lay-user) compared to YSI using capillary whole blood (Calf)			
		n	230
		Slope (95% CI)	0.9855 (0.973 – 0.999)
		y-int. (mg/dL) (95% CI)	7.0391 (3.618 – 10.460)
		r²	0.9899
		Range (mg/dL)	68 – 388

4. Clinical cut-off:

- Not applicable

5. Expected values/Reference range:

Status	Range
Before eating	<100 mg/dL (5.6 mmol/L)
1-2 Hours after meals	<140 mg/dL (7.8 mmol/L)

American Diabetes Association, Clinical Practice Recommendations (2013) Diabetes Care, Vol 36, Supplement 1, p S1 - S100

M. **Instrument Name:**

Element V Meter

N. **System Descriptions:**

1. Modes of Operation:

Each strip is single use and requires a sample volume of 0.3 µL.

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

Yes X or No .

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

Yes or No X .

2. Software

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

Yes X 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:

The glucose test is intended to be used with capillary whole blood from the finger, dorsal hand, ventral palm, forearm, upper-arm, calf and thigh only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

The meter is an auto-coding meter. No coding is required by the user. The user is required to verify that the code displayed on the meter and read off the test strip accurately reflects the code on the test strip vial.

6. Quality Control:

Three levels of control glucose solution are available. One level is included with the meter as a kit and 3 levels are sold separately. The user has to change the setting on the meter to identify a control sample so that the result is not inappropriately saved as a patient result.

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

1. Hematocrit Study: The effect of different hematocrit levels on the performance of the Element V Blood Glucose System was evaluated using venous whole blood samples with hematocrit levels 20, 30, 42, 50, and 60 %, and spiked or glycolyzed to achieve 6 glucose concentrations ranging from 28 to 568 mg/dL (28, 46, 66, 121, 181, 258, 368, 432, 521, and 568 mg/dL). Each sample was then tested 15 times using 15 Element V meters and one lot of test strips. The meter values were compared with those obtained from average YSI analyzer values. The biases relative to YSI were found to acceptable within the claimed hematocrit range of 20 to 60%.
2. Altitude study: Venous whole blood samples collected and adjusted to obtain 9 glucose concentrations of 44, 67, 118, 229, 268, 345, 402, 451, and 551 mg/dL were tested at the following conditions in an altitude chamber which evaluated both oxygen as well as pressure effects at sea level and 10,000 feet above sea level. The study included 5 meters and 1 test strip lot. Results were compared to YSI values. The results demonstrate acceptable bias and indicate acceptable performance to the claimed altitude of 10,000 ft.
3. Temperature and Humidity studies: The sponsor performed temperature and humidity studies using venous blood samples with glucose concentrations of 40, 116, 326

mg/dL to evaluate temperatures ranging from 10 to 40 °C (50 to 104 °F) and relative humidity from 10% to 90%. Meter results were compared to YSI values. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity, and high temperature/high humidity. No significant bias (relative to YSI) was observed with the temperature and humidity combinations tested. The results support a temperature claim of 10 to 40 °C (50 to 104 °F) and relative humidity from 10% to 90%.

4. Sample Volume: The sponsor performed a study to verify the test strip minimum sample volume requirement (0.3 µL) and the test strip fill error requirement established for the Element V Blood Glucose Monitoring System. The sponsor provided adequate software validation for the feature. Blood samples with glucose concentrations of 37, 66, 133, 256, and 464 mg/dL were tested at five sample volumes (0.2, 0.25, 0.3, 0.4, and 0.5 µL). Values obtained were compared to YSI values. Results support the claimed minimum sample volume of 0.3 µL.
5. Readability Evaluation: Flesch-Kincaid readability assessment was conducted and the results demonstrated that the User Manual, test strip package insert and control solution instruction for use were written at the 8th grade level or below.
6. Electromagnetic compatibility (EMC): Testing was performed by SK Tech Co., Ltd. The test report stated conformance to IEC 61326-1:2005, IEC 61326-2-6:2005
7. Infection Control Studies:
The system is intended for single-patient use only. CaviWipes (EPA registration #46781-8) were validated through disinfection efficacy studies demonstrating complete inactivation of hepatitis B virus (HBV) using materials comprising the meter. Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or in the external materials of the meter after 1,098 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 3 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.
8. Software documentation was reviewed and demonstrated that the device was developed under appropriate software lifecycle processes. The following documentation related to the software was reviewed and found to be acceptable: level of concern, software description, device hazard analysis, software requirements specifications, software design specification, software development environment description, traceability, and verification and validation testing.

P. Proposed Labeling:

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

Q. Conclusion:

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