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

A. 510(k) Number:
k133045

B. Purpose for Submission:
New device

C. Measurand:
Capillary whole blood glucose

D. Type of Test:
Quantitative Amperometric assay (Glucose Oxidase)

E. Applicant:
Infopia Co., Ltd

F. Proprietary and Established Names:
Element Lite Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345, Glucose test system
   21CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:
   Class II

3. Product code:
   NBW, System, Test, Blood Glucose, Over The Counter
   CGA, Glucose Oxidase, Glucose
   JJX, Quality control material (assayed and unassayed)

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

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

2. Indication(s) for use:
The Element™ Lite Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh. The Element™ Lite Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. The Element™ Lite 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 of diabetes or for neonatal use. Alternative site testing should be done only during steady–state times (when glucose is not changing rapidly).

The Element™ Lite Test Strips are for use with the Element™ Lite Meter to quantitatively measure glucose 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 thigh.

The Element™ Lite Control Solutions are for use with the Element™ Lite Meter and Element™ Lite Test Strips to check that the meter and test strips are working together properly and the test is performing correctly.

3. Special conditions for use statement(s):
   - The single-patient use system is for single-patient use only and should not be shared.
   - 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
   - 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:
   The Element™ Lite Blood Glucose Meter

I. Device Description:

The Element Lite Blood Glucose Monitoring System consists of an Element Lite Blood Glucose meter, Element Lite Blood Glucose Test Strips, Element Lite Blood Glucose Control Solutions, a user manual, logbook, carrying bag, a quick reference guide, and lancing device with reusable lancets.

The Element Lite Test Strips are identical to the predicate Element Test Strips with the exception of the size of the strip. The Element Lite Test Strips size is 5 mm (width) X 27 mm (length) were as the predicate is 6 mm (width) X 33 mm (length). The Element Lite Blood Glucose control solutions are available in three

concentrations: Level 1, Level 2 and Level 3. Level 2 is included in the system kit. Level 1 and Level 3 are purchased separately. The control solutions were previously cleared and stability and value assignment was previously established in k113670. The brand name of the glucose control solution has been updated to Element Lite Blood Glucose Monitoring Solution.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Element Blood Glucose Monitoring System

2. Predicate K number(s):

   k113670

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	Element Blood Glucose Monitoring System, (k113670)	Candidate Device Element Lite Blood Glucose Monitoring System
Similarities		
Intended Use/Indications for Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Calibration Coding	Auto coding	Same
Test range	20-600 mg/dL	Same
Hematocrit range	20-60%	Same
Sample type	Capillary whole blood	Same
Sample sites	Fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and thigh.	Same
Sample volume	0.3 µL	Same
Sample test time	3 seconds	Same
Memory Capacity	365 Tests	Same
Battery Type	Two 3.0 V CR2032 lithium batteries	Same

Differences		
Meter size	52 X 84.5 X 17	54 X 82 X 18
Meter Weight	48g	41g
Test Strip size *	6 mm (width) X 33 mm (length)	5 mm (width) X 27 mm (length)

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

- ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. (2003)
- ISO 13640 Stability testing of in vitro diagnostic medical devices (2002)
- CLSI EP05-A2 Evaluation of precision performance of quantitative measurement method; approved guideline (2004)
- CLSI EP06-A Evaluation of the Linearity Quantitative Analytical Method; proposed guideline (2005)
- CLSI EP07-A2 Interference Testing in Clinical Chemistry; approved guideline (2005)
- CLSI EP09-A2-IR Method comparison and bias estimation using patient samples; approved guideline (2002)

L. Test Principle:

The 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:

Within-run (Repeatability)

Venous blood from an EDTA anticoagulant tube was adjusted with an aqueous glucose solution to five concentrations (40 mg/dL, 83 mg/dL, 133 mg/dL, 208 mg/dL, 338 mg/dL) across the claimed range and tested on three lots of test strips on 10 meters. Concentrations were established on YSI 2300. Ten replicates were tested per meter, test strip lot and glucose concentration. Results are summarized below:

Glucose Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
40	100	1	38	1.4	3.7
		2	39	1.4	3.6
		3	41	1.2	2.9
83	100	1	79	1.8	2.3
		2	78	2.3	2.9
		3	81	2.4	3.0
133	100	1	142	3.4	2.4
		2	143	3.5	2.4
		3	140	3.3	2.4
208	100	1	206	3.4	1.7
		2	210	2.9	1.4
		3	209	3.3	1.6
338	100	1	342	5.3	1.5
		2	339	4.7	1.4
		3	346	5.0	1.4

Intermediate Precision

The intermediate precision evaluation was performed with three concentrations of control solution (46 mg/dL. 105 mg/dL, and 308 mg/dL). Ten replicates per day were performed on three lots of test strip, used on ten meters, over a 20 day period. The control sample value was determined using YSI 2300 Auto Analyzer. Results are summarized below:

Glucose Level (mg/dL)	n	Strip Lot	Mean (mg/dL)	SD (mg/dL)	%CV
46	600	1	47	1.5	3.2
		2	44	1.3	3.0
		3	45	1.3	2.9
105	600	1	112	4.1	1.7
		2	112	1.9	1.9
		3	112	2.1	1.9
308	600	1	317	6.2	2.0
		2	317	6.2	2.0
		3	308	6.2	1.8

b. Linearity/assay reportable range:

The sponsor performed linearity studies using adjusted venous blood samples with 14 different glucose concentrations to include the following: 19.8, 28.9, 47.1, 56.2, 65.3, 83.6, 92.7, 165.6, 238.4, 311.3, 384.3, 457.1, 529.9 and 602.8 mg/dL. For each concentration, 15 consecutive tests (with 5 measurements per lot) by Element Lite Blood Glucose Monitoring System and 2 measurements with the YSI 2300 Auto analyzer were performed respectively. The resulting

data was compared and the linear regression analyses were as follows:

Lot 1: $y = 1.0029x - 2.106$, $R^2 = 0.9997$
Lot 2: $y = 0.9999x - 1.863$, $R^2 = 0.9997$
Lot 3: $y = 1.0036x - 1.816$, $R^2 = 0.9996$

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

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

Traceability:

The Element Lite Blood Glucose Monitoring System is traceable to the NIST SRM 917b reference material. The reference instrument used is the YSI 2300 Glucose analyzer and it is calibrated by YSI 2747 Glucose Standard which is a NIST traceable glucose standard.

Test Strip Stability:
The sponsor provided real-time and accelerated studies to verify the closed- and open- vial stability of the test strips. The stability studies were reviewed and found to be acceptable. The closed-vial claim is 24 months when stored at 36-86°F at 20 -60 % relative humidity. The open-vial stability claim is 3 months when stored at 36-86°F at 20-60 % relative humidity. The test strips should not be frozen.

Control Solution Value Assignment and Stability:

The control solutions were previously cleared and stability and value assignment was previously established in k113670. The controls are prepared at three target concentrations gravimetrically and the glucose concentrations are verified with the YSI reference method. The expected values are verified for each new lot of strips. The brand name of the glucose control solution has been updated to Element Lite Blood Glucose Monitoring Solution. The control solution can be stored once opened for up to three months at 46-86°F. The closed vial claim is 24 months from the manufactured date when stored at 46-86F°.

d. *Detection limit:*

See linearity study in Section M1b above.

e. *Analytical specificity:*
To assess potential interference the sponsor used venous whole blood samples adjusted to three glucose concentrations of 60 mg/dL and 115 mg/dL and 320

mg/dL. Each of these samples was divided into a test pool and a control pool and each of the potential endogenous and exogenous interfering substances was added to the test pool. Each substance was tested at a minimum of two concentrations, normal/therapeutic and high/toxic concentrations. Each sample was analyzed in replicates of 5. The % difference between the test sample and the control sample was calculated. The results are summarized below:

Potential Interfering Substance	**Concentration at which no significant interference is observed (mg/dL) (typical conc)**
Acetaminophen	20
Ascorbic acid	6
Bilirubin	40
Cholesterol	500
Creatinine	5
Dopamine	0.09
Ethanol	400
Galactose	50
Gentisic acid	1.8
Glutathione	3
Hemoglobin	200
Ibuprofen	50
Levo-Dopa	13
Maltose	300
Salicylic acid	60
Tetracycline	1.5
Tolbutamide	65
Tolazamide	5
Triglycerides	3000
Urea	260
Uric acid	23

The following interference warnings are included in the labeling:

- Interferences: Acetaminophen, uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Lipemic samples: Cholesterol up to 500 mg/dL or triglyceride up to 3000 mg/dL do not significantly affect the results. Values beyond these levels should be interpreted with caution.

f. Assay cut-off:
Not applicable.

2. Comparison studies:
a. Method comparison with predicate device:

A user performance study was performed to compare the lay user self-test results to the YSI method. The study was performed at three clinical sites and all participants were given the user manual in English with no further information or coaching provided. Participants were then asked to perform testing using the glucose meter. 150 participants performed testing by taking samples from the fingertip, dorsal hand, forearm, and calf. 170 participants performed testing by taking samples from the ventral palm, upper arm, and thigh. A technician then collected capillary blood from each participant for measurement on YSI. The range of glucose values tested was 58-519 mg/dL. Three test strip lots were tested in the study. Participant results using the meter were compared to YSI and are summarized by sample site below:

Fingerstick:

User performance results for glucose concentrations < 75mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
13	7/13 (54%)	12/13 (92 %)	13/13 (100 %)

User performance results for glucose concentrations ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
137	73/137 (53%)	116/137 (85%)	132/137 (96%)	137/137 (100%)

$y = 0.9971x - 2.7559$, $R^2 = 0.9845$

Ventral palm:

User performance results for glucose concentrations < 75mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
23	16/23 (70%)	21/23 (91%)	23/23 (100%)

User performance results for glucose concentrations ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
147	70/147 (48%)	121/147 (82%)	141/147 (96%)	147/147 (100%)

$y = 1.0078x + 5.9171$, $R^2 = 0.995$

Dorsal hand:

User performance results for glucose concentrations < 75mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
4	2/4 (50%)	4/4 (100%)	4/4 (100%)

User performance results for glucose concentrations ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
146	62/146 (42%)	111/146 (76%)	140/146 (96%)	146/146 (100%)

$y = 0.9935x + 12.06$, $R^2 = 0.9897$

Upper arm:

User performance results for glucose concentrations < 75mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
24	17/24 (71%)	22/24 (92%)	24/24 (100%)

User performance results for glucose concentrations ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
146	73/146 (50%)	118/146 (80%)	143/146 (98%)	146/146 (100%)

$y = 0.9858x + 7.7528$, $R^2 = 0.971$

Forearm:

User performance results for glucose concentrations < 75mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
4	¾ (75%)	4/4 (100%)	4/4 (100%)

User performance results for glucose concentrations ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
146	61/146 (42%)	112/146 (77%)	139/146 (95%)	146/146 (100%)

$y = 0.9973x+9.7365$, $R^2 = 0.9893$

Calf:

User performance results for glucose concentrations < 75mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
4	1/4 (25%)	4/4 (100%)	4/4 (100%)

User performance results for glucose concentrations ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
146	68/146 (47%)	113/146 (77%)	141/146 (97%)	146/146 (100%)

$y = 0.9927x+10.093$, $R^2= 0.9876$

Thigh:

User performance results for glucose concentrations < 75mg/dL

Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
24	17/24 (71%)	22/24 (92%)	24/24 (100%)

User performance results for glucose concentrations ≥ 75 mg/dL

Number of test results	Within ± 5%	Within ± 10 %	Within ± 15 %	Within ± 20 %
146	98/146 (67%)	130/146 (89%)	142/146 (97%)	146/146 (100%)

$y = 1.0010x+0.7741$, $R^2= 0.985$

b. Matrix comparison:
Not applicable

3. Clinical studies:

a. Clinical Sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data:
Not applicable.

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	<100 mg/dL
1-2 hours after meals	<140 mg/dL

Reference: American Diabetes Association. *Diabetes Care Vol* 36 (Supp. 1) January 2013, p S1-S100.

N. Instrument Name:
The Element Lite Blood Glucose meter

O. System Descriptions:
1. Modes of Operation:
Each test 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 _____.

The proposed device transmits data to the GlucoDiary data management system, which was previously cleared in k130181.

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 _____.

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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 ventral palm, dorsal hand, upper arm, forearm, calf and thigh. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:
   The meter is autocoded, therefore no coding is required by the user. The coding circuit printed on the test strip is consistent with the code in the meter and the meter detects the code of the strip.

6. Quality Control:
   Three levels of aqueous glucose control solutions are available with this system (Level 1, Level 2, and Level 3). Control solution Level 2 is provided with the kit. An acceptable range for each control level is printed on the test strip vial label. Recommendations on when to test the control materials are provided in the labeling and what the user should do if the control result falls outside these ranges.

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

1) Hematocrit Study:
   Venous blood samples were obtained, centrifuged, and divided into plasma and red blood cells in order to adjust the hematocrit to obtain the following 5 percentage: 20%, 30%, 42%, 50%, 60%. The concentration of glucose was adjusted in each hematocrit percentage to the following 10 levels: 23, 42, 70, 116, 175, 256, 372, 441, 513, 550 mg/dL through either glycolysis or analytical spiking. Each sample was tested 15 times using 15 different Element Lite Blood Glucose Monitoring Systems. The plasma glucose value of sample was measured by YSI 2300 analyzer and the hematocrit of the sample was measured by NOVA STAT profile. The % biases relative to YSI were acceptable within the claimed hematocrit range of 20 - 60%.

2) Altitude study:
To evaluate the effects of altitude on the Element Lite Blood Glucose Monitoring System, 1 test strip lot was tested on 5 meters using venous from 18 donors that was spiked or glycolized to nine glucose concentrations (41, 64, 115, 226, 264, 355, 406, 449, 501 mg/dL). The samples were tested at 10,000 feet in an altitude chamber which adjusts both pO2 level and pressure, and at sea level (0 feet) as a control. Results obtained were compared with those obtained with the reference method (YSI). The results demonstrate acceptable bias to the reference to support the claims in the labeling that altitudes up to 10,000 feet have no significant effect on blood glucose measurements from the BGMS.

3) Sample volume study:
The sponsor performed a study to verify the minimum test strip sample volume requirement for the Element Lite Blood Glucose Meter. Blood samples were tested at four sample volumes (0.25, 0.3, 0.4, and 0.5), using five concentrations of adjusted and unaltered blood samples (39, 65, 131, 254, and 461 mg/dL) and values obtained were compared to YSI values. Results support the claimed minimum sample volume of 0.3µL

4) Temperature and humidity studies:
Temperature and humidity operating conditions were evaluated for temperatures ranging from 50-104˚F (10-40˚C) and relative humidity from 10% to 90% in the following combinations
10℃, RH 10% (lowest temperature / lowest humidity)
40℃, RH 10% (highest temperature / lowest humidity)
10℃, RH 90% (lowest temperature / highest humidity)
40℃, RH 90% (highest temperature / highest humidity)
Protocol and acceptance criteria were provided and found to be acceptable. The results supported the Sponsor's claimed operating temperature from 50-104˚F and relative humidity range from 10% to 90%.

5) Infection Control Studies:
The Element Lite Blood Glucose Monitoring System is intended for single-patient use only. CaviWipesTM Disinfecting Towelettes with EPA registration number 46781-8 were validated demonstrating complete inactivation of live virus for use with the meter. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 1,095 cleaning and disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate cleaning and disinfecting once per day for 3 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6) EMC testing: The subject device is the same as the predicate device, ElementTM Blood Glucose Monitoring System (k113670), in rated current and PCB structure. Electromagnetic compatibility and electrical safety were established in k113670.

7) Flesch-Kincaid readability assessment was conducted and the results demonstrated that the User Manual, test strip package insert and control solution package insert were written at the 8th grade level.

8) Customer support is available Monday through Friday 9:00 am to 9:00 pm EST by calling 1-888-446-3246.

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.