

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

**A. 510(k) Number:**

K060793

**B. Purpose for Submission:**

Reduction in test time and software modifications to eliminate or modify some features available in previously cleared meter

**C. Measurand:**

Glucose

**D. Type of Test:**

Quantitative, Glucose Oxidase, Electrochemical Biosensor

**E. Applicant:**

Home Diagnostics, Inc.

**F. Proprietary and Established Names:**

Element Blood Glucose Test System

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1345, Glucose Test Systems

2. Classification:

Class II

3. Product code:

NBW – System, Test, Blood Glucose, Over the Counter  
CGA – Glucose Oxidase, Glucose

4. Panel:

75 Clinical Chemistry

**H. Intended Use:**

1. Intended use(s):

See Indication for Use below

2. Indication(s) for use:

The Element Blood Glucose Test System is intended for the quantitative determination of glucose in human whole blood taken from the finger or forearm. The system is intended to be used to assist the patient and healthcare professional in the management of diabetes.

3. Special conditions for use statement(s):

For at home use and for use by healthcare professionals in physician's offices and convalescent care bedside testing facilities.

4. Special instrument requirements:

Element Blood Glucose meter

**I. Device Description:**

The Element Blood Glucose Test System is comprised of the Element Blood Glucose Meter, Element Test Strips, and Element Control Solutions (low and high).

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

TrueTrack Smart System

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

K030703, K032657

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Quantitative measurement of glucose in human whole blood from finger or forearm by people with diabetes and healthcare professionals	Same
Reagent	Glucose oxidase	Same
Sample size	1 ul	Same
Measurement range	20-600 mg/dL	Same
Test strips	Identical, new name	
Control solutions	Identical, new name	

Differences		
Item	Device	Predicate
Meter memory display	50 blood or control results	365 blood results, 1 control result
Calculate and display morning averages	Not available	Available
Test time	5 seconds	10 seconds
Units of measure	Factory set	Programmed by user
Date/time in display	Not available	Available
Data upload capability	Serial port not accessible to user	Serial port accessible to user

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

None referenced.

**L. Test Principle:**

Glucose measurement is based on the electrical potential caused by the reaction of glucose in the sample with reagents contained on the test strip's electrodes. The glucose in the sample is oxidized by glucose oxidase, producing gluconolactone and the reduced form of an electron mediator. The amount of reduced mediator is proportional to the amount of glucose present in the sample. The reduced electron mediator is then oxidized at the surface of the measurement electrodes when a specified voltage is applied across the electrodes by the meter. The resulting current is measured and converted to a glucose concentration by the meter and displayed as a plasma equivalent value

## **M. Performance Characteristics (if/when applicable):**

The only performance characteristics applicable to this submission are precision and accuracy, to demonstrate that measurements at 5 seconds (Element meter) are equivalent to measurements at 10 seconds (TrueTrack meter). The remaining performance characteristics are unaffected by the current modifications and remain the same as those presented in the predicate 510(k)s.

### **1. Analytical performance:**

#### ***a. Precision/Reproducibility:***

Pooled blood at 3 levels (70, 98 and 215 mg/dL) were tested on both meters using 3 lots of test strips. The overall % CV for 5 replicates of each level run on the Element meter was compared to the same results on the TrueTrack meter. Acceptance criteria = at 70 mg/dL, mean CV must be  $\leq 9.8\%$ ; at 98 mg/dL and 215 mg/dL, mean CV must be  $\leq 8.3\%$ . Results of this study showed that the average within vial % CV was  $< 6.0\%$  at all levels for each strip lot, and the between vial % CV was  $< 5.0\%$ .

#### ***b. Linearity/assay reportable range:***

The linearity/assay reportable range was cleared with the TrueTrack Smart System (K030703 and K032657).

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

Traceability, stability and expected values cleared with the TrueTrack Smart System (K030703 and K032657).

#### ***d. Detection limit:***

The detection limit was cleared with the TrueTrack Smart System (K030703 and K032657).

#### ***e. Analytical specificity:***

Analytical specificity was cleared with the TrueTrack Smart System (K030703 and K032657).

#### ***f. Assay cut-off:***

Not applicable

### **2. Comparison studies:**

#### ***a. Method comparison with predicate device:***

Pooled blood adjusted to 9 glucose levels, ranging from 30-535 mg/dL, was run with 3 test strip lots on both meters. Accuracy was demonstrated by the comparison of Element regression statistics against True Track using the same

samples. Acceptance criteria = slope of regression line must be  $1.00 \pm 0.10$ ; y intercept must be  $0.0 \pm 10.0$ ; and the correlation coefficients must be  $\geq 0.950$ . Each of the 3 strip lots must meet the criteria. The following results were obtained:

	<b>Acceptance limits</b>	<b>Lot 1619</b>	<b>Lot 1620</b>	<b>Lot 1621</b>
<b>Slope</b>	0.90 to 1.10	1.00	0.99	1.02
<b>Y Intercept</b>	$-10$ to $+10$	2.6	1.4	0.5
<b>R<sup>2</sup></b>	0.95 to 1.00	0.999	0.999	0.999

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):

Performance in the hands of lay users was cleared with the TrueTrack Smart System (K030703 and K032657).

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected values/ reference range provided with TrueTrack Smart System (K030703 and K032657).

**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.