

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

A. 510(k) Number:

K033627

B. Purpose for Submission:

New device

C. Analyte:

Glucose

D. Type of Test:

Quantitative, electrochemical biosensor

E. Applicant:

Biomedix, Inc.

F. Proprietary and Established Names:

Q. Steps Biometer G Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1345, Glucose Test System
2. Classification:
Class II
3. Product Code:
CGA, Glucose Oxidase, Glucose
JJX, Single (Specified) Analyte Controls (Assayed and Unassayed)
4. Panel:
Chemistry 75

H. Intended Use:

1. Intended use(s):
See Indications for Use below.
2. Indication(s) for use:
The Q. Steps Biometer G Blood Glucose Monitoring System is intended to be used for quantitative measurement of glucose in fresh capillary whole blood from the fingertip for all ages (excluding neonates). It is intended for use outside the body (for in vitro diagnostic use) by healthcare professionals in settings such as clinical laboratories and physician office laboratories as an aid to monitor the effectiveness of diabetes control.
3. Special condition for use statement(s):
For use by healthcare professionals only

4. Special instrument Requirements:
N/A

I. Device Description:

The Q .Steps Biometer G Blood Glucose Monitoring System is comprised of the Q. Steps Biometer G meter, Q. Steps Glucose Test Strips, Q. Steps Control Solution and BD Lancet device.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Lifescan One Touch Basic Blood Glucose Monitoring System
2. Predicate K number(s):
K031472
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Test principle	Based on glucose oxidase	same
Differences		
Item	Device	Predicate
Intended use	For use by healthcare professionals use	For use by healthcare professionals as well as lay persons with diabetes
Technology	amperometric	photometric
Test memory	99 result capacity	75 result capacity
Sample volume	5 ul	10 ul
Measurement range	50 - 400 mg/dL	0 – 600 mg/dL
Test time	15 seconds	45 seconds
Hematocrit range	30 – 60%	25 – 60%

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

None referenced

L. Test Principle:

The test system uses enzymatic electrochemical biosensor technology. When a drop of blood is applied to the test strip, the oxidation of D-glucose catalyzed by *Aspergillus niger* causes electron transfer at the electrode surfaces. A current is generated and detected by the meter. The magnitude of the current generated is proportional to the glucose in the sample.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Using commercial glucose reference solutions, 5 concentrations were measured for each level. Two measurements were performed twice daily for 20 days.

Glucose level (mg/dL)	N	Mean	SD	%CV
50	80	54.09	2.38	4.40
80	80	83.20	2.01	2.42
120	80	121.19	4.89	4.03
200	80	201.23	5.92	2.94
375	80	369.34	6.95	1.88

b. *Linearity/assay reportable range:*

Testing was conducted using venous whole blood spiked to five levels of glucose concentration across the measuring range of the device. Four replicates of each level were run on 3 lots of test strips. The bias of the Q. Steps Biometer G vs YSI were calculated. The mean bias at 45 mg/dL was 8.2% and at 400 mg/dL was 5.2%.

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

N/A

d. *Detection limit:*

N/A

e. *Analytical specificity:*

Interference testing was conducted to determine the effect of 23 select endogenous and exogenous substances. Stock solutions of the substances were prepared and added to venous blood samples spiked to two glucose concentrations and standardized to 45% hematocrit. Control samples were aliquots of the spiked venous samples with no added interferants. Paired differences were analyzed to determine statistically significant differences between two lots of test strips. A p value of < 0.5 was considered to be statistically significant. Interference was observed only in higher than therapeutic dosages of acetaminophen, ascorbic acid, L-Dopa, Dopamine, Methyldopa, and Tolazamide.

f. *Assay cut-off:*

N/A

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

Two hundred capillary blood samples were tested at 4 sites by healthcare professionals using the Q Steps Biometer G, One Touch Basic, and YSI. The range of samples tested was 55 – 465 mg/dL. The linear regressions were as follows:

$$\text{Q. Steps vs One Touch} \quad y = 0.92x + 9.67, r = 0.97$$

Q. Steps vs YSI

$$y = 0.96x + 0.94, r = 0.98$$

b. *Matrix comparison:*

N/A/

3. Clinical studies:

a. *Clinical sensitivity:*

N/A

b. *Clinical specificity:*

N/A

c. *Other clinical supportive data (when a and b are not applicable):*
see section 2.a.

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

70 – 110 mg/dL, fasting, non-diabetic

less than 160 mg/dL, one hour after meal

less than 140 mg/dL, 2 hours after meal

- referenced from Joslin Diabetes Manual

N. Conclusion:

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