

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

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

k100437

**B. Purpose for Submission:**

Addition of alternative site testing to a previously cleared device (k090389)

**C. Measurand:**

Capillary whole blood glucose

**D. Type of Test:**

Quantitative, glucose oxidase

**E. Applicant:**

Bestgen Biotech Corporation

**F. Proprietary and Established Names:**

AP-1000 Blood Glucose Monitoring System

AP-1000multi 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 - Blood glucose test system, over the counter

CGA - Glucose oxidase, glucose test system

4. Panel:

75-Clinical Chemistry

**H. Intended Use:**

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

AP-1000 Blood Glucose Monitoring System

The AP-1000 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. The AP-1000 Blood Glucose Monitoring Systems is intended to be used by a single person and should not be shared. The AP-1000 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. AP-1000 Blood Glucose Test Strips must be used with the AP-1000 Meter. AP-1000 Meter is intended to be used by a single person and should not be shared. AP-1000 Meter is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000 Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. AP-1000 Blood Glucose Test Strips must be used the AP-1000 Blood Glucose Meter. AP-1000 Blood Glucose Test Strips are intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

AP-1000multi Blood Glucose Monitoring System

The AP-1000multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and

from the alternative sites (palm, forearm, upper arm, calf, and thigh). The AP-1000multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use) and is intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system is only used with single-use, auto-disabling lancing device. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000multi Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh). AP-1000multi Blood Glucose Test Strips must be used with the AP-1000multi Meter. AP-1000multi Meter is intended for testing outside the body (in vitro diagnostic use) and is intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000multi Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh). AP-1000multi Blood Glucose Test Strips must be used with the AP-1000multi Meter. AP-1000multi Blood Glucose Test Strips are intended for testing outside the body (in vitro diagnostic use) and are intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

3. Special conditions for use statement(s):

Testing is done outside the body (*in vitro* diagnostic use). The alternative site testing (palm, forearm, upper arm, calf, and thigh) in this system can be used only during steady-state blood glucose conditions. Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations. The device is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. Not for use on critically ill patients, patients in shock, dehydrated patients, hypotensive patients or hyperosmolar patients.

4. Special instrument requirements:

Bestgen Biotech Corporation, AP-1000 and AP-1000multi Blood Glucose Meters.

**I. Device Description:**

The AP-1000 Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-1000 test strips and MAJOR control solution with the AP-1000 Blood Glucose Monitoring System.

The AP-1000multi Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-1000multi test strips and MAJOR control solution with the AP-1000multi Blood Glucose Monitoring System.

Both systems (AP-1000 and AP-1000multi) utilize an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions. The control solutions and the test strips were previously cleared under k090389. The systems allow the palm, forearm, upper arm, calf, and thigh to be used as alternative testing sites.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

AP-1000 Blood Glucose Monitoring System

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

k090389

3. Comparison with predicate:

<b>Comparison Table</b>		
<b>Item</b>	<b>Device (k100437)</b>	<b>Predicate (k090389)</b>
Indications for Use	For the quantitative measurement of glucose, as an aid to monitor the effectiveness of diabetes control.	same
Testing Site	fingertips AST: palm, forearm, upper arm, calf, and thigh	fingertips
Detection method	Amperometry	same
Enzyme	Glucose Oxidase ( <i>Aspergillus niger</i> )	same
Measurement range	20-600 mg/dL	same
Sample volume	0.6 µL	same
Reaction time	6 seconds	same
Meter dimensions	54(L) x 93(W) x 16(H)	same
Meter weight	53 g with battery	same
Hematocrit	30-55%	same
Operating conditions	10-40°C, 20-80% R.H.	same
Coding	Internal coding	same
Memory feature	960 measurements	same

**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.

**L. Test Principle:**

The AP-1000/AP-1000multi Blood Glucose Monitoring Systems use electrochemical methodologies. The system quantitatively measures blood glucose levels using an amperometric method, which involves detecting the current produced from glucose oxidation. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

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

1. Analytical performance:

a. *Precision/Reproducibility:*

Refer to the analytical performance characteristics described in the 510(k) Substantial Equivalence Determination Decision Summary for k090389.

b. *Linearity/assay reportable range:*

Refer to the analytical performance characteristics described in the 510(k) Substantial Equivalence Determination Decision Summary for k090389.

The reportable range of the AP-1000 Blood Glucose Monitoring System was confirmed to be 20 to 600 mg/dL.

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

Refer to the analytical performance characteristics described in the 510(k) Substantial Equivalence Determination Decision Summary for k090389.

The unopened shelf-life of the Major Glucose Control Solutions (previously cleared under k090389) is 24 months and the open vial stability is 90 days at the recommended storage of 36-86 °F. The unopened shelf-life of the AP-1000 blood glucose test strips is 18 months and the open vial stability is 90 days at the recommended storage of 36-86 °F.

d. *Detection limit:*

The measuring range of the AP-1000 and AP-1000multi glucose monitoring systems is 20 to 600 mg/dL.

e. *Analytical specificity:*

Refer to the analytical performance characteristics described in the 510(k) Substantial Equivalence Determination Decision Summary for k090389.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Refer to the analytical performance characteristics described in the 510(k) Substantial Equivalence Determination Decision Summary for k090389 for evaluation of system accuracy and lay-user performance.

To demonstrate performance of the new device when testing alternative sites, the sponsor conducted a new user performance evaluation including the following testing sites: finger, palm, forearm, upper arm, calf, and thigh. One set of performance data was evaluated since the AP-1000 and AP-1000multi systems use the same test strips and are identical with the exception of their names and indications for use (single- vs. multiple-patient use). Results were compared to a reference method (YSI-2300) and subjected to acceptance criteria described in the ISO 15197 standard.

User Performance Evaluation of Alternative Site Testing:

In the user performance study, 100 subjects measured their own blood glucose on the AP-1000 glucose monitoring system using samples from the finger and the following alternative testing sites: palm, forearm, upper arm, calf, and thigh. Healthcare professionals then tested these samples using the YSI-2300 reference method. The study was performed with five AP-1000 glucose monitoring systems throughout a glucose concentration range of 41.5 to 452 mg/dL. The regression statistics and accuracy data are summarized in tables below.

<b><u>Regression Statistics</u></b>			
	<b>Slope</b>	<b>Intercept</b>	<b>R</b>
Finger (vs. YSI)	1.0032	-1.2248	0.9953
Palm (vs. YSI)	1.0125	-2.5308	0.9961
Forearm (vs. YSI)	1.0079	-1.6339	0.9959
Upper Arm (vs. YSI)	1.0089	-1.4833	0.9969
Calf (vs. YSI)	1.0104	-2.0046	0.996
Thigh (vs. YSI)	0.9983	-1.0961	0.9962

<b><u>Study Results</u></b>
Glucose < 75 mg/dL

	Within $\pm$ 5 mg/dL	Within $\pm$ 10 mg/dL	Within $\pm$ 15 mg/dL	
Finger (vs. YSI)	14/14 (100%)	14/14 (100%)	14/14 (100%)	
Palm (vs. YSI)	14/14 (100%)	14/14 (100%)	14/14 (100%)	
Forearm (vs. YSI)	13/14 (93%)	14/14 (100%)	14/14 (100%)	
Upper Arm (vs. YSI)	14/14 (100%)	14/14 (100%)	14/14 (100%)	
Calf (vs. YSI)	12/14 (86%)	14/14 (100%)	14/14 (100%)	
Thigh (vs. YSI)	12/14 (86%)	14/14 (100%)	14/14 (100%)	
<b>Glucose <math>\geq</math> 75 mg/dL</b>				
	Within $\pm$ 5 %	Within $\pm$ 10 %	Within $\pm$ 15 %	Within $\pm$ 20%
Finger (vs. YSI)	75/86 (87%)	86/86 (100%)	86/86 (100%)	86/86 (100%)
Palm (vs. YSI)	74/86 (86%)	86/86 (100%)	86/86 (100%)	86/86 (100%)
Forearm (vs. YSI)	75/86 (87%)	86/86 (100%)	86/86 (100%)	86/86 (100%)
Upper Arm (vs. YSI)	76/86 (88%)	86/86 (100%)	86/86 (100%)	86/86 (100%)
Calf (vs. YSI)	74/86 (86%)	85/86 (99%)	86/86 (100%)	86/86 (100%)
Thigh (vs. YSI)	72/86 (84%)	86/86 (100%)	86/86 (100%)	86/86 (100%)

*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):*

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected blood glucose values for nondiabetic adults are as follows:

Before eating	< 100 mg/dL
Two hours after meals	< 140 mg/dL

Reference: American Diabetes Association: Diabetes Care, Volume 34, Supplement 1, January 2011, S11-S61.

**N. Instrument Name:**

Bestgen Biotech Corporation, AP-1000/ AP-1000multi Blood Glucose Meters

**O. System Descriptions:**

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

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

Yes \_\_\_\_\_ or No  X

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:

This device is intended to be used with capillary whole blood from the finger palm, forearm, upper arm, calf, and thigh which can be applied directly to the test strip.

5. Calibration:

The device must be coded with the code found on the current test strip label. No further calibration is required.

6. Quality Control:

The sponsor has two levels of controls supplied with this meter. When a test strip is inserted into the meter, each control can be measured by following the instructions for “Quality Control Testing” provided in the User Manual for the meter. An acceptable range for each control level is printed on the test strip vial label. The user is instructed to contact Customer Service if the control results fall outside these ranges.

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

1. A readability assessment was conducted and the results showed that the labeling was written at the 8<sup>th</sup> grade level.
2. Customer service is available between 8:30 am and 5:30 pm-Pacific Standard Time, Monday through Friday. Users are instructed to contact their healthcare providers outside hours of operation. The toll free US phone number is 1-888-873-1021 for customer support.
3. The device is intended for single- (AP-1000 Blood Glucose Monitoring System) and multiple-patient use (AP-1000multi Blood Glucose Monitoring System). Caviwipes disinfecting Towelettes with EPA registration #46781-8 were validated by virucide efficacy testing using Hepatitis B surface antigen (HBsAg) with the meter and lancing device (for use only with the single-patient use system). The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 18,250 cleaning and disinfection cycles for the meter (5000 cycles for the lancing device) designed to simulate 5 years of device use. Each robustness cycle tested consisted of one pre-clean wipe and one disinfecting wipe. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

**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.