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

A. 510(k) Number:
k103044

B. Purpose for Submission:
Appearance and name change of a previously cleared device (k090389)

C. Measurand:
Capillary whole blood glucose from the finger

D. Type of Test:

Quantitative, amperometric, glucose oxidase

E. Applicant:
Bestgen Biotech Corp.

F. Proprietary and Established Names:
AP-1010/AP-1010multi and AP-1020/AP-1020multi Blood Glucose Monitoring Systems

G. Regulatory Information:
1. Regulation section:
   21 CFR 862.1345 Glucose Test System
2. Classification:
   Class II
3. Product code:
   NBW - system, test, blood glucose, over the counter
   CGA - glucose oxidase, glucose
4. Panel:
   Chemistry (75)

H. Intended Use:
1. Intended use(s):
   See indication(s) for use below

2. Indication(s) for use:
   AP‑1010 Blood Glucose Monitoring System

   The AP‑1010 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP‑1010 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The AP‑1010 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‑1010 Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP‑1010 Blood Glucose Test Strips must be used with the AP‑1010 Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

AP‑1010multi Blood Glucose Monitoring System

The AP‑1010multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP‑1010multi Blood Glucose Monitoring System 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 should only be used with single‑use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP‑1010multi Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP‑1010multi Blood Glucose Test Strips must be used with the AP‑1010multi Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). This system should only be used with single‑use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

AP‑1020 Blood Glucose Monitoring System

The AP‑1020 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP‑1020 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The AP‑1020 Blood Glucose Monitoring Systems 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‑1020 Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP‑1020 Blood Glucose Test Strips must be used with the AP‑1020 Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

AP‑1020multi Blood Glucose Monitoring System

The AP‑1020multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP‑1020multi Blood Glucose Monitoring System 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 should only be used with single‑use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP‑1020multi Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood sample drawn from the fingertips. AP‑1020multi Blood Glucose Test Strips must be used with the AP‑1020multi Blood Glucose Meter. Testing is done outside the body (In Vitro diagnostic use). This system is only used with single‑use lancing devices. 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):
   Prescription and OTC

   - It 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.
   - Multiple patient use device should only use single use, auto disabling lancing devices.
   - Single-patient use device is for use on single-patient use only and should not be shared

4. Special instrument requirements:
   AP-1010/AP-1010multi and AP-1020/AP-1020multi Blood Glucose Meters

I. Device Description:

The AP-1010/AP-1010multi Blood Glucose Monitoring Systems consist of three main products: the meter, test strip, and control solutions. Only AP-1010 and AP-1010multi test strips and MAJOR control solutions are to be used with the AP-1010 and AP-1010multi Blood Glucose Monitoring Systems.

The AP-1020/AP-1020multi Blood Glucose Monitoring Systems consist of three main products: the meter, test strip, and control solutions. Only AP-1020 and AP-1020multi test strips and MAJOR control solution are to be used with the AP-1020 and AP-1020multi Blood Glucose Monitoring Systems.

All systems 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 MAJOR Level I/Level II Control Solutions were previously cleared under k090389.

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:

Comparison Table		
Item	Device (k103044)	Predicate (k090389)
Indications for Use	For the quantitative measurement of glucose, as an aid to monitor the effectiveness of diabetes control.	same
Testing Site	fingertips	same
Detection method	Amperometry	same
Enzyme	Glucose Oxidase (Aspergillus niger)	same
Measurement range	20-600 mg/dL	same
Sample volume	0.6 – 1.0 uL	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

Comparison Table		
Item	Device (k103044)	Predicate (k090389)
Coding	Internal coding	same
Memory feature	960 measurements	same
User interface	same	same
Position of Function buttons	same	same
Shape of Function buttons	different	different

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-1010/AP-1010multi and AP-1020/AP-1020multi Blood Glucose Monitoring Systems use electrochemical methodologies. These systems quantitatively measure 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):

Performance data are not required for the appearance and name change of the previously cleared device (k090389). The AP-1010 and AP-1020 systems include the same meter and test strips as the multi versions – the only difference is in the names due to the different indications for use (single vs. multiple-patient use)

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Refer to the analytical performance characteristics described in k090389.

   b. *Linearity/assay reportable range:*

      Refer to the analytical performance characteristics described in k090389.

      The reportable range is 20 to 600 mg/dL.

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

Refer to the analytical performance characteristics described in k090389.

d. Detection limit:

Based on the measuring range is 20 to 600 mg/dL.

e. Analytical specificity:

Refer to the analytical performance characteristics described in k090389.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Refer to the analytical performance characteristics described in k090389 .

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):

No lay user studies were required for the design changes to the device. The user input configurations remain the same. Essentially the input buttons remain the same in size except for minor shape change.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected blood glucose values for nondiabetic adults are as follows:

Fasting	< 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:

AP-1010/AP-1010multi and AP-1020/AP-1020multi 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 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:

Refer to the Hematocrit, Altitude, Temperature/Humidity, and Electrical Magnetic Compatibility and Safety studies described in k090389.

Labeling in this submission has been confirmed to be at Flesch-Kincaid Grade Level of 7.4.

The device is intended for single- (AP-1010 and AP-1020 Blood Glucose Monitoring Systems) and multiple-patient use (AP-1010multi and AP-1020multi Blood Glucose Monitoring Systems). 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.