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

A. 510(k) Number:

k103230

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, amperometric method, Glucose Oxidase

E. Applicant:

Bestgen Biotech Corporation

F. Proprietary and Established Names:

AP-3000 Blood Glucose Monitoring System
AP-3000multi Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
CGA, glucose oxidase, glucose	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
NBW, system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
JJX, single (specified) analyte controls (assayed and unassayed)	Class I, reserved	21 CFR § 862.1660	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

AP-3000 Blood Glucose Monitoring System

The AP-3000 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 at home. The AP-3000 Blood Glucose Monitoring Systems is intended for testing outside the body (*in vitro* diagnostic use). It is intended for use by lay users and should only be used by a single patient as an aid to monitor the effectiveness of diabetes control. It is intended to be used by a single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-3000 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 at home. AP-3000 Blood Glucose Test Strips must be used with the AP-3000 Meter. The AP-3000 Meter is intended for testing outside the body (*in vitro* diagnostic use). It is intended for use by lay users and should only be used by a single patient as an aid to monitor the effectiveness of diabetes control. It is intended to be used by a single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-3000 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 at home. AP-3000 Blood Glucose Test Strips must be used with the AP-3000 Blood Glucose Meter. The AP-3000 Blood Glucose Test Strips are intended for self testing outside the body (*in vitro* diagnostic use). It is intended for use by lay users and should only be used by a single patient as an aid to monitor the effectiveness of diabetes control. It is intended to be used by a single person and should not be shared. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution is for use with AP-3000 meter and AP-3000 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

AP-3000multi Blood Glucose Monitoring System

The AP-3000multi 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-3000multi Blood Glucose Monitoring Systems is intended for testing outside the body (*in vitro* diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use, auto-disabling

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-3000multi 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-3000multi Blood Glucose Test Strips must be used with the AP-3000multi Meter. AP-3000multi Meter is intended for testing outside the body (*in vitro* diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use, auto-disabling 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-3000multi 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-3000multi Blood Glucose Test Strips must be used with the AP-3000multi Meter. AP-3000multi Blood Glucose Test Strips are intended for testing outside the body (*in vitro* diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. This system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution is for use with AP-3000multi meter and AP-3000multi Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):

    - Testing is done outside the body (*in vitr*o 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.
    - 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.
    - AST value should not be used to calibrate Continuous Glucose Monitors (CGMs) or entered into an insulin-dosing calculator for determining insulin dose.
    - 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-3000 Blood Glucose Meter and AP-3000 Blood Glucose Test Strips
    AP-3000multi Blood Glucose Meter and AP-3000multi Blood Glucose Test Strips

Disposable, single use lancet devices are used with the AP-3000multi BGMS.

I. Device Description:

The AP-3000 Blood Glucose Monitoring System consists of the AP-3000 Blood Glucose Meter, AP-3000 Blood Glucose Test Strips, MAJOR Control Solutions (Level I and II), lancing device, User's Guide and Quick Guide. The AP-3000 Blood Glucose Meter must be calibrated with the code found on the test strip vial label. This device can be used to measure fresh capillary blood from the finger, or alternative sites (palm, forearm, upper arm, calf, and thigh).

The AP-3000multi Blood Glucose Monitoring System consists of the AP-3000multi Blood Glucose Meter, AP-3000multi Blood Glucose Test Strips, MAJOR Control Solutions (Level I and II), single use lancing devices, User's Guide and Quick Guide. The AP-3000 Blood Glucose Meter must be calibrated with the code found on the test strip vial label. This device can be used to measure fresh capillary blood from the finger, or alternative sites (palm, forearm, upper arm, calf, and thigh).

J. Substantial Equivalence Information:

Predicate device name	Predicate 510(k) number
AP-1000 Blood Glucose Monitoring System	k090389

Comparison with predicate:

Similarities and Differences		
Item	Device (k103230)	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 and alternate site testing (palm, forearm, upper arm, calf, and thigh)	Fingertips
Detection Method	Amperometry	Same
Enzyme	Glucose Oxidase (Aspergillus niger)	Same
Measurement Range	20 to 600 mg/dL	Same
Hematocrit Range	20 to 60%	30-55%
Sample Volume	0.7 µl	0.6 µl
Reaction Time	7 seconds	6 seconds
Memory	448 measurements	960 measurements
Temperature Range	50 to 104^{o}F	Same
Humidity Range	0 to 85%	20 to 80%

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-3000 and AP-3000multi Blood Glucose Monitoring Systems use electrochemical methodologies. The 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):

The AP-3000 and AP-3000multi Blood Glucose Monitoring Systems are the same meters and use the same test strip; however they have separate names due to their different indications for use (single- vs. multiple-patient use).

1. Analytical performance:

a. Precision/Reproducibility:

Within-run precision was measured by using five spiked venous whole blood samples (hematocrit ranging from 35% to 50%). Each sample was tested on three lots of test strips on ten meters. Ten replicates were tested per meter, test strip lot, and glucose concentration, (n=100 tests per test strip lot). Results are summarized below:

Sample	Mean (mg/dL)	Strip Lot	SD (mg/dL)	%CV
1	46	1	2.3	5.3
		2	2.2	5.0
		3	2.2	5.0
2	95	1	2.4	2.6
		2	2.3	2.5
		3	2.4	2.6
3	129	1	2.3	1.9
		2	2.2	1.8
		3	2.5	2.0
4	230	1	5.5	2.5
		2	5.9	2.6
		3	5.9	2.6
5	350	1	10.6	3.0
		2	10.3	2.9
		3	10.7	3.0

Between-day precision was measured by reading three levels of control solutions.

Each sample was tested on three lots of test strips, twenty replicates per day for ten days using ten meters, (n=200 tests per test strip lot). Results are summarized below:

Sample	Mean (mg/dL)	Strip Lot	SD (mg/dL)	%CV
1	45	1	2.2	5.1
		2	2.5	5.6
		3	2.6	5.8
2	125	1	2.9	2.4
		2	3.0	2.5
		3	2.7	2.2
3	325	1	7.2	2.2
		2	7.1	2.2
		3	6.8	2.1

b. Linearity/assay reportable range:

A linearity study was performed using ten spiked venous whole blood samples with the following concentrations: 10, 19, 42, 72, 123, 172, 260, 366, 480 and 595 mg/dL, which ranged from 10 to 595 mg/dL. All samples were tested on three lots of test strips, ten meters (ten measurements per test strip lot), on the AP-3000 Blood Glucose Meter. Glucose concentrations were tested on the YSI 2300 analyzer to generate the expected values. The observed values were plotted against the expected values and an appropriate line fitted by standard linear regression was generated with results summarized below:

Linear Regression Analysis:

Lot 1: $y = 0.9793x + 0.989$, $r^2 = 0.9992$.

Lot 2: $y = 0.9677x + 2.171$, $r^2 = 0.9993$.

Lot 3: $y = 0.9764x + 1.064$, $r^2 = 0.9996$.

Based upon the results, the sponsor claims a measurement range of 20 to 600 mg/dL for the AP-3000 and AP-3000multi Blood Glucose Monitoring System

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

Two levels of Control Solution (Level I and II) are included with each test kit. For each glucose control solution, a reference measurement was taken using an YSI 2300 analyzer. One hundred fifty measurements obtained with candidate meters were performed (30 bottles * 5 measurements/per bottle) for each glucose control solution and the mean value, SD and CV were calculated. Level I and II glucose control solutions were found to have ranges of 70-77 mg/dL and 200-215 mg/dL, respectively.

Stability characteristics of both levels of Glucose Control Solutions were determined using real time studies. The open vial stability was evaluated at 2, 25 and 30^{o}C (all temperatures at 50% humidity), while the unopened vial stability was evaluated at 25^{o}C (50% humidity). The sponsor claimed open vial stability of 90 days stored at 2 to 30^{o}C and an unopened vial stability of 20 months stored at 25^{o}C.

The stability characteristics of the test strips were evaluated in real-time open and closed vial studies. Open vial stability was determined by evaluating test strips stored at three temperature s (4, 30 and 40°C; 60% humidity) during a 100 day period. Closed vial stability was determined by evaluating test strips stored at three temperatures (4, 25 and 40°C; 50% humidity) during a 20 month period. Based upon their results, the sponsor claims an open vial stability of 90 days and an unopened shelf-life stability of 20 months stored at 4 to 40°C.

d. Detection limit:

The measuring range of the AP-3000 and AP-3000multi Blood Glucose Monitoring System is 20 to 600 mg/dL. This range was verified by the linearity study (see section M.1.b.).

e. Analytical specificity:

Interference testing of exogenous and endogenous substances was performed using a protocol based on CLSI EP7-A. A venous blood sample (hematocrit level of 40 ±2%) was adjusted to two different glucose concentrations (125 and 250 mg/dL). Each potential interfering substance was added at several concentrations to an aliquot of each of the two glucose concentrations (test) and compared to the same sample without the potential interfering substance (control). Each interferent-glucose sample was tested using ten different meters and three lots of test strips. The YSI 2300 glucose analyzer was used as the reference method. The results are as follows:

The following substances up to concentrations listed shall have no significant effect on test results (≤±10% difference)	
Acetaminophen	0.5 mg/dL
Ascorbic Acid	1.2 mg/dL
Bilirubin, Conjugated	20 mg/dL
Cholesterol	500 mg/dL
Creatinine	30 mg/dL
Dopamine	1.0 mg/dL
Ibuprofen	40 mg/dL
L-DOPA	1.0 mg/dL
Tetracycline	4.0 mg/dL
Tolbutamide	100 mg/dL
Triglyceride	3,000 mg/dL
Uric Acid	2.0 mg/dL

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted an accuracy study, AP-3000 Blood Glucose Monitoring

System versus YSI-2300 Glucose Analyzer, at a single site with 100 patients over 10 days (10 patients per day) using two glucose meters and one test strip lot. A healthcare professional collected fingertip capillary blood into EDTA tubes. A portion of the collected sample was used to measure glucose concentration on an YSI-2300 Glucose Analyzer.

The total range of samples tested was 26.9 to 442 mg/dL, with a hematocrit range of 41-45%. Five samples <50 mg/dL and five samples >430 mg/dL were glycolyzed or spiked, respectively. Linear regression results are presented below:

Linear Regression Analysis:

Meter #1: $y = 1.0764x - 8.8568$, $r^2 = 0.9964$, n = 100

Meter #2: $y = 1.0785x – 9.1703$, $r^2 = 0.9969$, n = 100

For glucose concentrations <75 mg/dL			
User	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Meter #1	11/15 (73%)	15/15 (100%)	15/15 (100%)
Meter #2	13/15 (87%)	15/15 (100%)	15/15 (100%)

For glucose concentrations ≥75 mg/dL				
User	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Meter #1	67/85 (79%)	84/85 (99%)	85/85 (100%)	85/85 (100%)
Meter #2	67/85 (79%)	85/85 (100%)	85/85 (100%)	85/85 (100%)

AST Testing Data

The sponsor conducted a consumer study and alternative site testing study. At a single site, the sponsor conducted alternative site studies on palm, forearm, upper arm, calf and thigh with a total of 150 lay users. Each participant obtained samples from their fingertip, palm, forearm, upper arm, calf and thigh and tested these samples on the AP-3000 Blood Glucose meter using only the instructions in the user's manual and test strip insert. A healthcare professional collected blood from fingertip, palm, forearm, upper arm, calf and thigh and tested the sample using the same meter. Venous blood was also collected by healthcare professional and measured on an YSI-2300 Glucose Analyzer. Linear regression results from lay users and professionals are presented below.

AST Site	User	Linear Regression Results	Sample Size (n)
Finger	Lay User	$y = 1.033x - 3.962$, $r^2 = 0.9908$	150
Palm	Lay User	$y = 0.9922x – 0.3956$, $r^2 = 0.983$	150
Forearm	Lay User	$y = 0.985x + 0.8029$, $r^2 = 0.9813$	150
Upper arm	Lay User	$y = 0.9607x + 2.7539$, $r^2 = 0.9808$	150
Calf	Lay User	$y = 0.9818x + 1.1073$, $r^2 = 0.9802$	150
Thigh	Lay User	$y = 0.9812x + 1.0691$, $r^2 = 0.98$	150
Finger	Professional	$y = 1.0144x – 1.1774$, $r^2 = 0.9916$	150
Palm	Professional	$y = 0.9913x + 0.0034$, $r^2 = 0.987$	150

Forearm	Professional	$y = 0.9685x + 2.2785$, $r^2 = 0.9928$	150
Upper arm	Professional	$y = 0.9611x + 2.9187$, $r^2 = 0.9821$	150
Calf	Professional	$y = 0.9666x + 2.8303$, $r^2 = 0.9807$	150
Thigh	Professional	$y = 0.9985x – 0.2978$, $r^2 = 0.981$	150

All alternative site results met the ISO 15197 accuracy criteria where ninety-five percent (95%) of the individual glucose results fell within ±15mg/dL of the YSI results at glucose concentrations <75mg/dL and within ±20% at glucose concentrations ≥75mg/dL.

For glucose concentrations <75 mg/dL				
AST Site	User	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Finger	Lay User	8/8 (100%)	8/8 (100%)	8/8 (100%)
Palm	Lay User	8/8 (100%)	8/8 (100%)	8/8 (100%)
Forearm	Lay User	8/8 (100%)	8/8 (100%)	8/8 (100%)
Upper arm	Lay User	7/8 (88%)	8/8 (100%)	8/8 (100%)
Calf	Lay User	8/8 (100%)	8/8 (100%)	8/8 (100%)
Thigh	Lay User	6/8 (75%)	8/8 (100%)	8/8 (100%)
Finger	Professional	8/8 (100%)	8/8 (100%)	8/8 (100%)
Palm	Professional	8/8 (100%)	8/8 (100%)	8/8 (100%)
Forearm	Professional	8/8 (100%)	8/8 (100%)	8/8 (100%)
Upper arm	Professional	8/8 (100%)	8/8 (100%)	8/8 (100%)
Calf	Professional	8/8 (100%)	8/8 (100%)	8/8 (100%)
Thigh	Professional	8/8 (100%)	8/8 (100%)	8/8 (100%)

For glucose concentrations ≥75 mg/dL					
AST Site	User	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Finger	Lay User	137/142 (96%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Palm	Lay User	122/142 (86%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Forearm	Lay User	118/142 (83%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Upper arm	Lay User	107/142 (75%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Calf	Lay User	107/142 (75%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Thigh	Lay User	105/142 (74%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Finger	Professional	139/142 (98%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Palm	Professional	128/142 (90%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Forearm	Professional	120/142 (85%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Upper arm	Professional	118/142 (83%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Calf	Professional	110/142 (77%)	142/142 (100%)	142/142 (100%)	142/142 (100%)
Thigh	Professional	109/142 (77%)	142/142 (100%)	142/142 (100%)	142/142 (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, p. S11-S61.

N. Instrument Name:

AP-3000 Blood Glucose Meter and AP-3000multi Blood Glucose Meter

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 AP-3000 and AP-3000multi Blood Glucose Meters must be calibrated with the code found on the current test strip vial label. No further calibration is required.

6. Quality Control:

   The sponsor has two levels of controls (Level I and II) 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:

- A usability study was performed to assess the readability of the labeling for the US market by surveying the 150 lay users that participated in the study. Participants varied in age, education, and gender. These lay users also completed a questionnaire to response to whether the device is easy to use and the 'Instructions for use' were written in a way that makes it easy to use. The majority of the users responded that the device is very easy to use.
- Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User's Guide, test strip package insert and control solution package insert) was written at the 8th grade level.
- 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.
- The device is intended for single (AP-3000 Blood Glucose Monitoring System) and multiple-patient use (AP-3000multi Blood Glucose Monitoring System). Caviwipe Disinfecting Towelettes (Metrex Research Corporation, EPA registration #46781-8) were validated demonstrating complete inactivation of Hepatitis B surface antigen for

use with the blood glucose meter and the 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.

- EMC testing was evaluated and certified by Electronics Testing Center and a test report was submitted stating that the AP-3000 passed all tests; dated July 30, 2010.
- Temperature and humidity operating conditions were evaluated for temperatures ranging from -20 to 50^{o}C and relative humidity ranging from 0 to 93%. Protocol and acceptance criteria were provided and found to be acceptable. The results support the sponsor's claimed operating temperature of 4 to 40^{o}C and humidity range of 0 to 85%.
- A study was conducted to evaluate the effect of altitude of the AP-3000 BGMS. A venous blood sample adjusted to five different glucose concentrations (54, 81, 126, 271 and 453 mg/dL) was tested on two meters and a single lot of test strips. Each venous blood sample was evaluated by the YSI 2300 glucose analyzer. Tests were performed at six different elevations (sea level, 2624 feet, 4921 feet, 6266 feet, 7119 feet and 10,742 feet). The meter readings obtained were compared to the YSI method, the percent bias against the YSI results was calculated and all results were found to support the sponsor claims that the AP-3000 BGMS can be used at altitudes up to 10,742 feet.
- A study was conducted to evaluate the potential interference from hematocrit using seven different hematocrit levels (15%, 20%, 30%, 40%, 50%, 60% and 70%). For each hematocrit level, five different glucose concentrations (10, 70, 170, 285 and 450 mg/dL) were tested against the YSI-2300 Glucose Analyzer. Each glucose level/hematocrit combination was tested on twenty meters and two lots of test strips. The differences of the glucose meter results at each hematocrit/glucose combination were calculated against YSI-2300 Glucose Analyzer results at 40% hematocrit. The bias relative to YSI was acceptable to support the claim that hematocrit levels of 20 to 60% do not significantly affect the glucose results.
- A sample volume study was performed to verify the test strip sample volume requirement for the AP-3000 BGMS. A venous blood sample adjusted to three glucose concentrations (66, 105 and 230 mg/dL) was tested on one lot of test strips and ten meters. Each blood sample was applied to test strips at five sample volumes (0.6, 0.7, 0.8, 0.9, 1.0 and 1.1 µl). Protocols and acceptance criteria were provided and found to be acceptable. The sponsor concluded that sample volume of ≥0.7 µL produced accurate results.

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.