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

A. 510(k) Number:

k091815

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, glucose oxidase

E. Applicant:

Biotest Medical Corporation

F. Proprietary and Established Names:

SuperCheck 1 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:

   Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   Refer to indications for use below.

2. Indication(s) for use:

   The SuperCheck 1 Blood Glucose Monitoring System, Model 6268, is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home and as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis or screening for diabetes mellitus, and is not for use with neonates.

   The alternative site testing (forearm) in this system can only be used during steady-state blood glucose conditions.

   This system contains a speaking function that provides audible test results for users with low vision.

3. Special conditions for use statement(s):

   It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. For *in vitro* diagnostic use only, over-the-counter use, and prescription use. The device should not be used for patients who are dehydrated, in shock, critically ill, or experiencing a hyperglycemic-hypersmolar state.

4. Special instrument requirements:

   Biotest Medical Corp., SuperCheck 1 Blood Glucose Monitoring System

I. Device Description:

The SuperCheck 1 Blood Glucose Monitoring System, Model 6268, consists of a blood glucose meter, blood glucose test strips, control solutions, the lancing device, and lancets. The system is available either as a meter alone or as a kit. The control solutions were previously cleared under k032029. The meter comes with a speaking function that provides audible test results for users with low vision. The SuperCheck 1 Model 6268 allows the forearm to be used as an alternative site.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Prodigy Voice Blood Glucose Monitoring System

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

   k073118

3. Comparison with predicate:

Comparison Table		
Item	Device (k091815)	Predicate (k073118)
Indications for Use	The SuperCheck 1 Blood Glucose Monitoring System, Model 6268, is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home and as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, not for use with neonates. The alternative site testing (forearm) in this system can only be used during steady-state blood glucose conditions. This system contains a speaking function that provides audible test results for users with low vision.	The Prodigy Voice Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf, and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus. The alternative site testing in this system can be used only during steady-state blood glucose conditions. This system contains a speaking functionality which provides step by step instructions to aid visually impaired persons.
Detection method	Amperometry	same
Enzyme	Glucose Oxidase (Aspergillus niger)	same
Temperature compensation	Automatic compensation with built-in thermister	same

Comparison Table		
Item	Device (k091815)	Predicate (k073118)
Sample volume	0.7 uL	same
Reaction time	6 seconds	7 seconds
Measurement range	20-600 mg/dL	same
Meter dimensions	99(L) x 62(W) x 29(H)	95(L) x 55(W) x 18(H)
Meter weight	90 g	75 g
Operating conditions	10°C - 40°C, 20-80% R.H.	10°C - 40°C, Below 85% R.H.
Strip calibration	No coding. The meter and test strip have the same reference number printed on the meter box and on the test strip box and vial.	One code for all lots, with the user checking that the code number that appears on the meter display and on the test strip vial is correct.
Memory feature	500 measurements with day and time	450 measurements with day and time
Day average	7-, 14-, 28-, 60-, 90-day average glucose result	7-, 14-, 21-, 28-, 60-, 90-day average glucose result
Auto Shut Off	2 minutes	3 minutes
Alarm	Beeping sound and/or error message in LCD display	same
Communication	RS232 port	same
Speaking function	Yes	same
Strip vial open-vial stability	3-months	same

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

1. ISO 13640:2002. Stability Testing of *In Vitro* Diagnostic Reagents. (*In Vitro* Diagnostics).
2. EN 552:1994. Sterilization of medical devices. Validation and routine control of sterilization by irradiation.
3. EN 61326-1:2006. Electrical equipment for measurement, control, and laboratory use. EMC Requirements. General requirements.
4. ISO 10993-5:1999. Biological evaluation of medical devices, Part 5: Tests for *in vitro* cytotoxicity.
5. ISO 10993-10:2002. Biological evaluation of medical devices, Part 10: Tests for irritation and delayed-type hypersensitivity.
6. ISO 11137-1:1995. Sterilization of health care products. Requirements for validation and routine control of a sterilization process for medical devices.
7. ISO 14971:2007. Medical devices-Application of risk management to medical devices.
8. ISO 15197. *In vitro* diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
9. EN 60601-1-1. Medical electrical equipment, Part 1-1. General requirements for safety. Safety requirements for medical electrical systems.

10. EN 60601-1-2:2001 (A1:2006). Medical electrical equipment, Part 1-2. General requirements for basic safety and essential performance. Electromagnetic Compatibility.
11. EN 60601-1:1988 (A1:1991, A2:1995). Medical electrical equipment, Part 1. General requirements for safety.
12. EN 61010-1:2001. Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 1. General requirements.
13. IEC/EN 61010-2-101:2002. Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 2-101. Particular requirements for *in vitro* diagnostic (IVD) medical equipment.

L. Test Principle:

The test is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current and displays the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies to determine repeatability and intermediate precision were based on ISO 15197 standard. A repeatability study was conducted using blood samples at five different levels of glucose ranging from 49 to 391 mg/dL on three different reagent system lots, four packages per lot. Ten replicate measurements were obtained for each concentration and for each of twelve meters. An intermediate precision study was conducted using control material at three different glucose levels ranging from 46 to 366 mg/dL on three different reagent system lots, four packages per lot. Measurements were obtained for each concentration and for each of twelve meters for a period of ten days. The mean, standard deviation (SD), and coefficients of variation (CV) were determined for each sample, see results below:

Repeatability Data Summary					
Sample	**1**	**2**	**3**	**4**	**5**
Grand Mean (mg/dL)	49	90	128	246	391
Pooled SD (mg/dL)	0.64	0.79	1.02	1.63	3.12
Pooled CV	1.31%	0.88%	0.80%	0.66%	0.80%

Intermediate Precision Data Summary			
Sample	**1**	**2**	**3**
Grand Mean (mg/dL)	43	123	366
Pooled SD (mg/dL)	0.65	1.28	3.51

Pooled CV	1.41%	1.04%	0.96%

b. Linearity/assay reportable range:

A linearity study based on CLSI EP6-A standard was conducted on whole blood samples at twelve different glucose levels ranging from 20 to 605 mg/dL. Duplicate measurements for each glucose level were conducted on each of ten meters, three strip lots, and 10 vials per strip lot. Regression analysis showed a linear relationship between the SuperCheck 1 glucose monitoring system and the YSI-2300 reference method. The linear regression was as follows: $Y=1.0034X + 7.958$, $r^2=0.9981$, $n=360$. The reportable range of the SuperCheck 1 glucose monitoring system was confirmed to be 20 to 600 mg/dL. If a sample is less than 20 mg/dL, the result is flagged by the meter as LO. If a sample result exceeds 600 mg/dL, the result is flagged by the meter as HI.

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

The stability of the SuperCheck 1 test strips was demonstrated by real-time stability studies. The unopened shelf life is 11 months and the open-vial stability is 3 months at the recommended storage temperatures of 8°C to 30°C.

Value assignment for use of the control solutions with the SuperCheck1 test strips is based on measurements using the YSI-2300 reference method after calibration with YSI 2747 calibrator solution (NIST SRM #917A Clinical Dextrose). The control solutions were previously cleared under k032029.

The acceptable ranges are printed on the test strip vial labels.

d. Detection limit:

The measuring range of the SuperCheck 1 glucose monitoring system is 20 to 600 mg/dL. This range was verified by the linearity study (see section M.1.b of this decision summary).

e. Analytical specificity:

Interferences Study: A study was performed based on the CLSI EP7-A standard to test for possible interference due to a number of endogenous and exogenous substances. Control samples spiked at glucose levels of 80 and 120 mg/dL were tested in five replicates with the SuperCheck 1 glucose monitoring system and in singlicate with the YSI-2300 reference method. Each potential interfering substance was evaluated using samples containing a low (80 mg/dL) and a high (120 mg/dL) glucose level and compared against a control pool after measurements on the SuperCheck 1 glucose monitoring system and the YSI-2300 reference method. The table below shows the levels with no interference when testing for glucose with the SuperCheck 1 glucose monitoring system:

Substance	Reference/Therapeutic Level	No Interference at Listed Level
Endogenous Substance		
Bilirubin	0.29~1.23 mg/dL	20.8 mg/dL
Cholesterol	114.2~201.2 mg/dL	483.8 mg/dL
Creatinine	0.6~1.3 mg/dL	6.3 mg/dL
Hemoglobin	100~200 mg/dL	500 mg/dL
Triglycerides	10.3~111.7 mg/dL	1183.8 mg/dL
Uric Acid	2.5~8.0 mg/dL	10.9 mg/dL
Exogenous Substance		
Acetaminophen	1~3 mg/dL	6.2 mg/dL
Ascorbic Acid	0.4~2.0 mg/dL	4.5 mg/dL
Caffeine	0.5~2.0 mg/dL	6 mg/dL
Dopamine	0.03 mg/dL	0.09 mg/dL
Ephedrine HCl	1 mg/dL	3.6 mg/dL
Ibuprofen	1~7 mg/dL	37.5 mg/dL
L-Dopa	5 mg/dL	1.9 mg/dL
Methyl-Dopa	0.10~0.75 mg/dL	1.5 mg/dL
Salicylate	36 mg/dL	115.5 mg/dL
Tetracycline	0.2~0.5 mg/dL	1.5 mg/dL
Tolbutamide	5.4~10.8 mg/dL	64 mg/dL
Anticoagulants		
EDTA	400 mg/dL	800 mg/dL
Heparin	4000 U/dL	8000 U/dL

The sponsor included the following limitation in the label:

Interference was observed for therapeutic level of L-Dopa. Uric acid, acetaminophen, ascorbic acid, and ibuprofen have no significant interference in normal therapeutic levels. However, the concentration in blood beyond the following levels may cause inaccurate results: uric acid (10.9 mg/dL), acetaminophen (6.2 mg/dL), ascorbic acid (4.5 mg/dL), and ibuprofen (37.5 mg/dL).

Hematocrit Study: A study was performed to evaluate the blood hematocrit (HCT) effect on the performance of the SuperCheck 1 glucose monitoring system across the measuring range of the assay. Whole blood samples were tested in duplicate with the SuperCheck 1 glucose monitoring system using three lots of strips/twelve vials per lot and eighteen meters. Glucose concentrations at each HCT level (30%, 32%, 35%, 40%, 46%, 50%, 56%, and 60%) were compared with results obtained with the YSI-2300 reference method. The data were within ± 10 mg/dL for glucose levels < 75 mg/dL and within ± 15% for glucose levels ≥ 75 mg/dL for the claimed HCT range. The sponsor included the following limitation in the label: Hematocrit in the range of 32-56% has been shown not to affect the glucose results. If you do not know your hematocrit level, consult with your healthcare professional.

Altitude Study: The effect of altitude was evaluated by testing whole blood samples at 120 and 240 mg/dL on the SuperCheck 1 glucose monitoring system using three lots of strips/ten vials per lot and ten meters. Glucose concentrations at different altitude levels were compared with results obtained with the Hemocue Glucose Analyzer reference method. The measurements were acceptable when compared to the reference method results. The sponsor included the following limitation in the label: The test strips may be used at altitudes up to 5,280 feet without an effect on test results.

Humidity Study: The effect of humidity on the performance of the SuperCheck 1 glucose monitoring system was evaluated at three glucose levels (Low-76.5-79.4 mg/dL; Medium-136-144 mg/dL; and High-329-338 mg/dL) using whole blood samples. Ten replicates were tested at each glucose level with the SuperCheck 1 glucose monitoring system using three lots of strip/ten vials per lot and ten meters. Glucose concentrations at each humidity level (20%, 40%, 60%, 80%, and 95% R.H.) were compared with results obtained with the YSI-2300 reference method. The study results demonstrated that humidity between 20% R.H. and 95% R.H. did not affect glucose measurements. Results fell within ± 7%.

Temperature Study: A study was performed to evaluate the effect of temperature on the performance of the SuperCheck 1 glucose monitoring at three glucose levels (Low-77.8-79 mg/dL; Medium-137-142 mg/dL; and High-325-335 mg/dL) using whole blood samples. Ten replicates were tested at each glucose level with the SuperCheck 1 glucose monitoring system using three lots of strip/ten vials per lot and ten meters. Glucose concentrations at each temperature level (10, 20, 30, and 40°C) were compared with results obtained with the YSI-2300 reference method. The study results demonstrated that temperatures between 10°C and 40°C did not affect glucose measurements. Results fell within ± 7%.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Comparison studies were performed with the YSI-2300 reference method. System accuracy, lay-user performance evaluation, and a visually impaired user study were performed. Results were subjected to acceptance criteria described in the ISO 15197 standard.

System Accuracy: In the method comparison study, samples from the finger and forearm of 159 subjects were used for blood glucose measurements by healthcare professionals. From these, 26 capillary whole blood samples were adjusted to achieve the extreme low and high glucose concentrations recommended in the ISO 15197

standard. Measurements obtained with the SuperCheck 1 glucose monitoring system were compared to those obtained with the YSI-2300 reference method. The study was performed with three SuperCheck 1 glucose monitoring systems. The accuracy data is summarized in tables below.

Accuracy Study Regression Statistics	Finger	Forearm
Number of samples (n)	159	159
Range of YSI Glucose Values (mg/dL)	25-500	25-500
Slope	1.0254	1.0094
Intercept	-0.5618	2.3951
Correlation coefficient	0.9972	0.9954
R square	0.9945	0.9908

Accuracy Study Results				
Glucose < 75 mg/dL				
	Within ± 5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL	
Finger Sample	10/19 (53%)	17/19 (89%)	19/19 (100%)	
Forearm Sample	12/19 (63%)	19/19 (100%)	19/19 (100%)	
Glucose ≥ 75 mg/dL				
	Within ± 5 %	Within ±10 %	Within ± 15 %	Within ± 20%
Finger Sample	98/140 (70%)	130/140 (93%)	138/140 (99%)	140/140 (100%)
Forearm Sample	72/140 (51%)	120/140 (86%)	135/140 (96%)	140/140 (100%)

Lay-user Study: In the user performance study, 134 subjects were used for blood glucose measurements from the finger and the forearm. Subjects were provided with instructions for use and tested their own capillary whole blood samples from both the finger and forearm using the SuperCheck 1 glucose monitoring system. Healthcare professionals then tested these samples using the SuperCheck 1 glucose monitoring system and the YSI-2300 reference method. The study was performed with three SuperCheck 1 glucose monitoring systems. The accuracy data is summarized in tables below.

Lay-user Study Regression Statistics		
Finger	User vs. Reference	User vs. Professional
Number of samples (n)	134	134
Range of YSI Glucose Values (mg/dL)	63-490	63-490
Slope	1.0685	1.0306
Intercept	-1.6786	-0.2492
Correlation coefficient	0.9902	0.9906
R square	0.9806	0.9813
Forearm	User vs. Reference	User vs. Professional

Number of samples (n)	134	134
Range of YSI Glucose Values (mg/dL)	63-490	63-490
Slope	1.0321	1.0226
Intercept	2.5219	-0.7381
Correlation coefficient	0.9869	0.9910
R square	0.974	0.982

Lay-user Study Results				
Glucose < 75 mg/dL				
Finger Sample	Within ± 5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL	
Patient (vs. YSI)	2/8 (25%)	7/8 (88%)	8/8 (100%)	
Professional (vs. YSI)	5/8 (63%)	8/8 (100%)	8/8 (100%)	
Forearm Sample	Within ± 5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL	
Patient (vs. YSI)	1/8 (13%)	4/8 (50%)	8/8 (100%)	
Professional (vs. YSI)	6/8 (75%)	8/8 (100%)	8/8 (100%)	
Glucose ≥ 75 mg/dL				
Finger Sample	Within ± 5 %	Within ±10 %	Within ± 15 %	Within ± 20%
Patient (vs. YSI)	40/126 (32%)	87/126 (69%)	112/126(89%)	123/126 (98%)
Professional (vs. YSI)	93/126 (74%)	116/126 (92%)	124/126 (98%)	126/126 (100%)
Forearm Sample	Within ± 5 %	Within ±10 %	Within ± 15 %	Within ± 20%
Patient (vs. YSI)	39/126 (31%)	77/126 (61%)	105/126 (83%)	120/126 (95%)
Professional (vs. YSI)	63/126 (50%)	107/126 (85%)	121/126 (96%)	126/126 (100%)

Visually Impaired User Study: Fifty subjects with visual impairment were enrolled and user performance testing was performed using the SuperCheck 1 glucose monitoring system and the YSI-2300 reference method. The subjects in this test included those with vision category from 1 to 5, diagnosed per WHO Guidelines as ICD Version 2007. User performance was evaluated with subjects using the device with audible English language instructions. Subjects tested themselves on one meter and then were tested by healthcare professionals. Usability of the device was evaluated by users with a questionnaire.

Visually Impaired User Study Regression Statistics	User vs. Reference	User vs. Professional
Number of samples (n)	50	50
Range of YSI Glucose Values (mg/dL)	64-342	64-342
Slope	1.0623	1.0161
Intercept	-5.2254	-1.5977
Correlation coefficient	0.9899	0.9971
R square	0.9799	0.9942

Visually Impaired User Study Results				
Glucose < 75 mg/dL				
	Within ± 5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL	
User (vs. YSI)	1/4 (25%)	3/4 (75%)	4/4 (100%)	
Glucose ≥ 75 mg/dL				
	Within ± 5 %	Within ±10 %	Within ± 15 %	Within ± 20%
User (vs. YSI)	24/46 (52%)	37/46 (80%)	44/46 (96%)	46/46 (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 plasma blood glucose values for normal, nondiabetic adults are as follows:

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

Reference: American Diabetes Association: Diabetes Care, January 2007, volume 30 (suppl. 1) S42-S47.

N. Instrument Name:

Biotest Medical Corp., SuperCheck 1 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. The labeling and user guide specify the lancet and the strip are for single use only and instruct the user to discard immediately after use.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:
   Yes __X__ or No _____

   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 and the forearm (AST) which can be applied directly to the test strip.

5. Calibration:

   No coding. The meter and test strip have the same reference number printed on the meter box and on the test strip box and vial.

6. Quality Control:

   The sponsor provides one level of control (Medium) with this glucose monitoring system. Two additional controls (Low and High) are available when requested by the customer using the contact information provided in the User Manual. When the test strip is inserted into the meter, each control can be measured by following the instructions for "Running a Control Solution Test" 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 a customer assistance line during operational hours or a healthcare provider outside hours of operation if the control results fall outside these ranges. Controls values and value ranges are assigned as described in section M.1.c of this decision summary.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

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.