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

A. 510(k) Number:

k123090

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose from the finger, palm and forearm

D. Type of Test:

Quantitative, Amperometric method, Glucose oxidase

E. Applicant:

General Life Biotechnology Co. Ltd.

F. Proprietary and Established Names:

BeneCheck™ Premium GLU Monitoring System

BeneCheck™ Premium PRO GLU Monitoring System

G. Regulatory Information:

Device	Product Code	Classification	Regulation Section	Panel
GLB BeneCheck™ Premium GLU Monitoring System	NBW, CGA (over the counter)	Class II	21 CFR § 862.1345, glucose test system, over the counter, Glucose oxidase,	75-Chemistry
BeneCheck™ Premium Control Solutions	JJX	Class I, reserved	21 CFR § 862.1660, Quality Control material	75-Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   BeneCheck™ Premium GLU Monitoring System

   The BeneCheck™ Premium GLU Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole samples drawn from the fingertip, palm and forearm. The GLB BeneCheck™ Premium GLU Monitoring System is intended for testing outside of body (in vitro diagnostic use) by people with diabetes at home (single patient used only), as an aid to monitor the effectiveness of a diabetes control program.

   The BeneCheck™ Premium GLU Monitoring System and should not be used for the diagnosis of, or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

   The BeneCheck™ Premium GLU Test Strips are for use with the BeneCheck™ Premium GLU Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

   The BeneCheck™ Premium GLU Control Solutions are for use with the BeneCheck™ Premium GLU Meter and BeneCheck™ Premium GLU Test Strips to verify that the meters and test strips are working together properly and that the test performs properly.

   BeneCheck™ Premium PRO GLU Monitoring System

   The BeneCheck™ Premium PRO GLU Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole samples drawn from the fingertip, palm and forearm. The GLB BeneCheck™ Premium PRO GLU Monitoring System is intended for testing outside of body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings, as an aid to monitor the effectiveness of a diabetes control program. The system should only be used with single-use, auto-disabling lancing devices.

   The BeneCheck™ Premium PRO GLU Monitoring System should not be used for the diagnosis of, or screening for diabetes, nor for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

   The BeneCheck™ Premium PRO GLU Test Strips are for use with the BeneCheck™ Premium GLU PRO Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

   The BeneCheck™ Premium PRO Control Solutions are for use with the BeneCheck™ Premium PRO GLU Meter and BeneCheck™ Premium PRO GLU Test Strips to verify that the meters and test strips are working together properly and that the test performs properly.

3. Special conditions for use statement(s):

   For in-vitro diagnostic use only (external use only).

   Do not use the test strips for the testing of neonates.

   Patients undergoing oxygen therapy may yield falsely low results.

   In situations of decreased peripheral blood flow, examples include but are not limited to severe dehydration, in shock, or in a hyperosmolar state (with or without ketosis), hypertension, the test results may be falsely low.

   Critically ill patients should not be tested by the BeneCheck™ Premium GLU and Premium PRO GLU meters.

   Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.

   BeneCheck™ Premium GLU Monitoring System is for single patient use.

   BeneCheck™ Premium PRO GLU Monitoring System is for multiple patient use in a professional healthcare setting by a healthcare provider.

4. Special instrument requirements:

   BeneCheck™ Premium GLU Meter

   BeneCheck™ Premium PRO GLU Meter

I. Device Description:

BeneCheck™ Premium GLU Monitoring System:

The BeneCheck™ Premium GLU Monitoring System Kit consists of BeneCheck™ Premium GLU Meter, BeneCheck™ Premium GLU Test Strips, BeneCheck™ Premium GLU Control Solution level 2, BeneCheck™ Lancing Device, BeneCheck™ Twist Lancets, adjustable AST cap, 3V lithium battery, quick reference guide, package inserts, user manual and a carry bag. Two other levels of control solutions (level 1 and 3) are available for testing the system and can be purchased separately.

BeneCheck™ Premium PRO GLU Monitoring System:

The BeneCheck™ Premium PRO GLU Monitoring System Kit consists of BeneCheck™ Premium PRO GLU Meter, BeneCheck™ Premium PRO GLU Test Strips, BeneCheck™ Premium PRO GLU Control Solution level 2, 3V lithium battery, quick reference guide, package inserts, user manual and a carry bag. Two other levels of control solutions (level 1 and 3) are available for testing the system and can be purchased separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   OneTouch® Ultra2 Blood Glucose Monitoring System

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

   K053529

3. Comparison with predicate:

The BeneCheck Premium and Premium PRO GLU Monitoring Systems have the following similarities and differences to the predicate device:

Items	Predicate Device	Candidate Devices	
Brand Name	OneTouch® Ultra2 Blood Glucose Monitoring System (k053529)	BeneCheck™ Premium GLU Monitoring System (k123090)	BeneCheck™ Premium PRO GLU Monitoring System (k123090)
Indications for Use	Intended for use in the quantitative measurement of glucose in fresh capillary whole blood from finger, palm and forearm as an aid in monitoring the effectiveness of diabetes control program.	Same	Same
Enzyme	Glucose Oxidase	Same	
Measurement principle	Electrochemical biosensor	Same	
Coding	Manual code number selection	No coding	
Sample application	Test strip capillary draw	Same	
Calibration	Plasma calibrated	Same	
Power	Two 3V CR2032 batteries	One 3V CR2032 battery	
Power saving	Automatic shutoff after 2 minutes of inactivity	Automatic shutoff after 3 minutes of inactivity	
Test range	20 mg/dL to 600 mg/dL	Same	
Hematocrit	30% to 55%	Same	
Altitude	Up to 10,000 feet	Same	
Operating conditions	43 to 111ºF (6 to 44ºC), 10 to 90% R.H.	50 to 104ºF (10 to 40ºC), 10 to 90% R.H.	
Transportation storage conditions	50 to 86ºF (10 to 30ºC), 10 to 90% R.H.	Same	
Weight	42.5g with batteries	49.7g with batteries	
Dimension	79mm (L) x 57.2mm (W) x 22.9mm (H)	95mm (L) x 57mm (W) x 17.5mm (H)	
Test time	5 seconds	8 seconds	
Test volume	1.0 µL	0.9 µL	
Memory	500 test results with day and time	360 test results with day and time, and 7, 14, 21 & 28 days average values	
Glucose units	mg/dL	Same	

Items	Predicate Device	Candidate Devices	
Brand Name	OneTouch® Ultra2 Blood Glucose Monitoring System (k053529)	BeneCheck™ Premium GLU Monitoring System (k123090)	BeneCheck™ Premium PRO GLU Monitoring System (k123090)
Monitor	LCD display	Same	
Backlight	Yes	No	
Control solution	Three levels (low, normal, high)	Three levels (1, 2 and 3)	
PC link Feature	Yes, download results using One Touch Diabetes Management Software	Not available	

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

ISO 14971: 2009 Application of risk management to medical devices

ISO 15197: 2003 In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

EN 61010-1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements

EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for IVD medical equipment

EN 60601-1:1998/A1:1991A2: 1995 Medical electrical equipment – Part 1: General requirements for safety

EN 60601-1:1990/A1:1993A2: 1995 Medical electrical equipment – Part 1: General requirements for safety

EN61326-2-6:2005 Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – IVD medical equipment

EN 60068-2-64:2008 Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance

EP6-A: 2003 Evaluation of the linearity of quantitative measurement procedures: a statistical approach; approved guideline

EP5-A: 1999 Evaluation of precision performance of clinical chemistry devices

EP9-A2: 2002 Method comparison and bias estimation using patient samples; approved guideline – second edition

ISO 5725-2: 1994 Accuracy (trueness and precision) of measurement methods and results – Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method

L. Test Principle:

BeneCheck™ Premium GLU Monitoring System is an electronic device that utilizes the electrical characteristic technology for measuring the glucose level in human blood. A

relatively small drop of blood is placed on a disposable test strip coated with Glucose Oxidase (GOD) which interacts with the software driven meter. Within eight seconds, the concentration of blood glucose will be shown on the digital display screen.

M. Performance Characteristics (if/when applicable):

Since BeneCheck™ Premium GLU and BeneCheck™ Premium PRO GLU Monitoring Systems are identical, only one set of performance studies were provided for both the systems.

1. Analytical performance:

   a. Precision/Reproducibility:

   The repeatability study was performed by three operators using venous whole blood (hematocrit ranged from 40 to 45%) at five different glucose concentrations. The final glucose concentration for the blood samples were confirmed by YSI2300. Each sample was tested ten times on ten meters with each of the three lots of test strips. Ten measurements were obtained per meter and test strip lot combination, and glucose concentration (N=300 per concentration level). The results are summarized below:

   Within-run Precision Summary
   Lot 1 (N=100)

Heparinized blood	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**
YSI2300 (mg/dL)	42.6	91.0	126.7	222.6	327.6
Overall Mean (mg/dL)	45.0	88.0	128.0	227.0	330
Overall SD (mg/dL)	1.9	2.55	3.8	7.26	9.24
Overall CV (%)	4.2%	2.9%	3.0%	3.2%	2.8%

   Lot 2 (N=100)

Heparinized blood	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**
YSI2300 (mg/dL)	42.6	91.0	126.7	222.6	327.6
Overall Mean (mg/dL)	44.0	91.0	126.0	228.0	332
Overall SD (mg/dL)	2.0	2.46	3.65	8.66	11.28
Overall CV (%)	4.4%	2.7%	2.9%	3.8%	3.4%

   Lot 3 (N=100)

Heparinized blood	**Level 1**	**Level 2**	**Level 3**	**Level 4**	**Level 5**
YSI2300 (mg/dL)	42.6	91.0	126.7	222.6	327.6
Overall Mean (mg/dL)	43.0	92.0	126.0	223.0	335
Overall SD (mg/dL)	2.0	3.31	4.66	7.36	11.39
Overall CV (%)	4.5%	3.6%	3.7%	3.3%	3.4%

   Intermediate precision studies were performed by three operators using three levels of control solutions. Each sample was tested on ten meters using three lots of test strips for ten days (N=300 per concentration level).

   Between-day Precision Summary

   Lot 1 (N=100)

Control Solutions	Level 1 (30~50 mg/dL)	Level 2 (96~144 mg/dL)	Level 3 (280~420 mg/dL)
Overall mean (mg/dL)	33.74	117.77	346.08
Overall SD (mg/dL)	2.03	3.87	10.1
Overall CV (%)	6.03%	3.29%	2.92%

Lot 2 (N=100)

Control Solutions	Level 1 (30~50 mg/dL)	Level 2 (96~144 mg/dL)	Level 3 (280~420 mg/dL)
Overall mean (mg/dL)	33.09	113.84	354.0
Overall SD (mg/dL)	2.79	4.36	10.55
Overall CV (%)	8.44%	3.83%	2.98%

Lot 3 (N=100)

Control Solutions	Level 1 (30~50 mg/dL)	Level 2 (96~144 mg/dL)	Level 3 (280~420 mg/dL)
Overall mean (mg/dL)	33.36	115.0	350.0
Overall SD (mg/dL)	1.52	4.4	10.43
Overall CV (%)	4.57%	3.83%	2.98%

b. Linearity/assay reportable range:

Ten venous blood samples were prepared by mixing a low glycolyzed sample (15 mg/dL) and a high spiked sample (622 mg/dL) to cover the device measuring range of 20 to 600 mg/dL (42.5% hematocrit). Glucose concentrations (16.2, 53.2, 92.1,,166.0, 247.3, 322.5, 397.0, 474.3, 558.0 and 622.0 mg/dL) were confirmed by the YSI2300. One operator performed the study using ten calibrated meter and ten vials of test strips each from three lots in duplicate (N=20 per test strip lot). The results from the linear regression analysis of the data are summarized below:

Test Strip lots	Slope (95% CI)	Intercept ()	Regression Coeff R^2
Lot 1	0.986 (0.986±0.04)	3.165	0.998
Lot 2	0.978 (0.978±0.018)	-0.108	1.000
Lot 3	0.977 (0.977±0.031)	4.049	0.998
Combined	0.981 (0.981±0.02)	2.368	0.998

Based on the linearity data, the claimed measurement range of the BeneCheck Premium Blood Glucose Monitoring System is 20 to 600 mg/dL.

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

BeneCheck Premium GLU Control Solutions:

Traceability and value assignment – The BeneCheck™ Premium GLU and PRO GLU Monitoring System's glucose assay is traceable to the N.I.S.T SRM 917c and the YSI-2300 STAT PLUS (glucose oxidase) analyzer.

Value assignment for the BeneCheck™ Premium GLU and PRO GLU Control Solutions is performed with ten BeneCheck™ Premium GLU meters using 20 vials of BeneCheck™ Premium GLU test strips from each of the three lots. The mean, standard deviation and CV are calculated for each new lot of control material. If the three CVs, each from three lots of test strips, are ≤5%, then the control range for each strip lot is calculated. If the CV is > 5%, the product is judged defective and discarded.

Stability - The sponsor has provided a control solution (levels - 1, 2 and 3) storage stability study protocol and acceptance criteria to support their storage stability claim for the open vial of 90 days and for shelf life of 24 months when stored at 50 ^{o}F to 86 ^{o}F (10^{o}C to 30^{o}C). The accelerated testing at 122^{o}F (50^{o}C) for 95 days of closed vial supports the shelf life of 24 months, and the real time testing is on-going. The real time testing of open vial supports the storage claim of 90 days.

BeneCheck™ Premium GLU Test Strips:

Stability - The sponsor has provided a test strip storage stability study protocol and acceptance criteria to support their storage stability claim for the open vial of 90 days and for shelf life of 24 months when stored at 50 ^{o}F to 86 ^{o}F (10^{o}C to 30^{o}C) and 10% to 90% RH. The accelerated testing at 122^{o}F (50^{o}C) for 90 days of closed vial supports the shelf life of 24 months, and the real time testing is on-going (180 days of testing completed). The real time testing of open vial supports the storage claim of 90 days.

This information is provided in the labeling of the test strips and control materials.

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on the linearity/assay reportable range study (section M.1.b).

e. Analytical specificity:

Interference study was designed according to CLSI EP7-A2 guideline.

Twenty six potential endogenous and exogenous interfering substances were evaluated by spiking venous blood (HCT 42.5%) to two levels of glucose concentrations within the ranges 60 - 100 mg/dL and 200 -300 mg/dL. The glucose samples were spiked with the potentially interfering compounds and tested on five meters using one test strip lot. Several concentrations of the interfering substances were tested. Bias was calculated as individual percent difference in glucose reading between the test and control concentration groups. Significant interference is defined by the sponsor as a bias > 10 % of the test samples from the control group.

The sponsor claims no significant interference (≤ 10% difference) for the substances

at concentrations shown in the table below:

Generic name	test concentration (within 10% bias) (mg/dl)	physiologic/ therapeutic range (or Upper Limit) (mg/dl)
Acetaminophen	8.25	1-3
Ascorbate	3.0	0.4-2
Bilirubin	20.0	0-0.3
Cholesterol	326	300
Creatinine	30.0	0.6-1.3
Dopamine	2.0	0.03
Galactose	30.0	
Gentisic acid	7.5	0.2-0.6
Glutathione	13.25	47–100 (intracellular)
Ibuprofen	50.0	1-7
Lactose	100.0	
Levo-Dopa	1.0	0.02-0.28
Maltose	100.0	
Methyl-Dopa	1.875	0.1-0.75
salicylic acid	60.0	10.1-30.1
Sucrose	50.0	0.06
Tetracycline	10.0	0.2-0.5
Tolazamide	7.5	1.6
Tolbutamide	100.0	4.3-24
Triglyceride	1500.0	29-316
urea	500.0	6.6-85.8
Uric acid	8.5	2.3-8.0
Xylitol	100.0	0.12
Xylose	20.0	

The sponsor has listed the following information in their labeling: Acetaminophen,L-ascorbate,bilirubin, total cholesterol, creatinine, dopamine, EDTA, gentisic acid, heparin, ibuoprofen, levo-dopa maltose, methyl-dopa, sucrose, tetracycline,tolbutamide, triglyceride, urea, uric acid, xylitol, xylose, lactose, galactose (when at physiological or normal therapeutic levels) do not significantly affect the results. However, abnormally high concentrations in blood may cause inaccurately high results.

Glutathione, salicylic acid, and tolazamide at physiologic/therapeutic range of concentration may give significant interference.

Lowest concentration of potentially interfering substances tested with significant observed interference: glutothione (26.5mg/dL), ibuorofen (12.5mg/ dL), levo-dopa (2.0mg/dL), maltose (75mg/dL), salicylic acid (15mg/dL), tolazamide (3.75mg/dL), tolbutamide (25mg/dL).

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Accuracy study was performed by healthcare professionals using capillary whole blood from the fingers of 123 patients. The samples were tested in singlicate using a meter and a test strip randomly from three lots of Premium test strips and two Premium glucose meters. Some samples in the high and low range were altered. All results were compared to the capillary blood samples by YSI. Results are summarized below:

Regression Analysis Professional testing (fingerstick) on Premium BGMS vs YSI

Slope	Intercept	R^2
1.004	-0.974	0.981

Healthcare Professional testing (fingerstick) vs YSI < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
12/13 (92.3%)	12/13 (92.3%)	13/13 (100%)

Healthcare Professional testing (fingerstick) vs YSI ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
37/110(33.6%)	81/110(73.6%)	101/110(91.8%)	109/110(99.1%)

Alternative site testing of palm and forearm was performed by healthcare professionals. For study details, refer to section M.3.c for lay user performance studies.

Regression Analysis Healthcare Professional Palm vs YSI; N=151

Slope	Intercept	R^2
1.014	0.974	0.985

Regression Analysis Healthcare Professional Forearm vs YSI; N=151

Slope	Intercept	R^2
0.997	+3.047	0.980

Healthcare Professional Palm and Forearm vs YSI < 75 mg/dL; N=151

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Palm	3/7 (42.86%)	7/7 (100%)	7/7 (100%)
Forearm	3/7 (42.86%)	7/7 (100%)	7/7 (100%)

Healthcare Professional Palm and Forearm vs YSI ≥ 75 mg/dL; N=151

	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
Palm	68/144 (47.22%)	124/144 (86.11%)	144/144 (100%)	144/144 (100%)
Forearm	61/144 (42.36%)	118/144 (81.94%)	144/144 (100%)	144/144 (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):

Lay User Performance Study:

Lay user studies for fingerstick, palm and forearm were performed by 151 lay users and healthcare professionals using fresh capillary blood samples at eight locations in US. Labeling was provided only in English and users followed it to perform the testing. The lay user first performed the testing of the finger, palm and forearm followed by the healthcare professional performing the testing. Then within 5 minutes, capillary whole blood samples were collected in heparin tubes, plasma was separated, frozen and sent for testing on YSI. The samples were tested using three lots of Premium test strips which were distributed randomly to the lay users. All results were compared to the YSI. Results are summarized below:

Regression Analysis Lay User Fingerstick vs YSI

Slope	Intercept	R^2
0.982	+3.147	0.983

Regression Analysis Lay User Palm vs YSI

Slope	Intercept	R^2
1.009	+0.606	0.985

Regression Analysis Lay User Forearm vs YSI

Slope	Intercept	R^2
0.985	+3.405	0.977

Lay User Fingerstick, Palm and Forearm vs YSI < 75 mg/dL

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Fingerstick	4/7 (57.1%)	7/7 (100%)	7/7 (100%)
Palm	3/7 (42.86%)	7/7 (100%)	7/7 (100%)
Forearm	3/7 (42.86%)	7/7 (100%)	7/7 (100%)

Lay User Fingerstick, Palm and Forearm vs YSI ≥ 75 mg/dL

	Within ± 5%	Within ± 10%	Within ± %15	Within ± 20%
Fingerstick	68/144 (47.22%)	124/144 (86.11%)	144/144 (100%)	144/144 (100%)
Palm	71/144 (49.31%)	126/144 (87.5%)	144/144 (100%)	144/144 (100%)
Forearm	64/144 (44.44%)	110/144 (76.39%)	144/144 (100%)	144/144 (100%)

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Expected blood glucose values for normal people without diabetes is cited from the literature[1] and presented in the labeling as follows:

   Fasting: <100 mg/dL

   Two hours after meal: <140 mg/dL

   [1]American Diabetes Association. Standards of Medical Care in Diabetes. Diabetes Care (2012), 35 (Supplement 1): S11-S63.

N. Instrument Name:

BeneCheck Premium Glu meter

BeneCheck Premium PRO Glu meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.9 µL.

   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:

The glucose test is intended to be used with capillary whole blood from the finger, palm and forearm. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The BeneCheck Premium Glu meter and the BeneCheck Premium PRO Glu meter are autocoding devices.

6. Quality Control:

   The BeneCheck Premium Glu and BeneCheck Premium PRO Glu control solutions at three concentration levels (1, 2, 3) can be run with this device. The meter has to be set in control solution test mode to prevent control results from being stored in the internal memory as patient result. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. A labeling comprehension study was performed as a part of the lay user clinical study. The recruited 152 lay users (aged 18-83 yrs old) were provided with all labeling in English for the US market and a questionnaire. Participants varied in age, education, country of origin, and both men (n = 90) and women (n = 62) were included in the study. These lay users completed the questionnaire to indicate 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.

2. Flesch-Kincaid readability assessment was conducted and the results showed that the labeling (User manual, Quick Guide, test strip package insert and control solution package insert) were written at grade levels ranging from 7.0^{th} to 8.0^{th} grade.

3. The effect of different hematocrit levels on the accuracy of the device was evaluated on the Premium Blood Glucose Monitoring System using eight meters (tested in eight replicates) and three lots of test strips. Venous blood samples at six hematocrit levels from 25% to 60% (25, 30, 42.5, 50, 55 and 60%) were evaluated at four concentrations of glucose (47, 97, 222 and 455 mg/dL. Individual glucose concentrations were compared to mean YSI and normal HCT (42.5%) values and individual percent biases were calculated. Results demonstrated that hematocrit levels between 30 to 55% do not significantly interfere with glucose measurements.

4. Customer support is available 24 hours a day, 7 days a week at the toll-free telephone number 1-800-123-4567.

5. Minimum sample volume studies were performed at volumes starting from 0.7 µL to 1.5 µL (i.e. 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4 and 1.5 µL) using 30 vials of test strips from two lots. Three glucose concentrations of venous blood at 63.6, 109.5 and 267.0 mg/dL, as determined by the YSI, were tested. Each sample was tested with 5 meters in singlicate (N= 5 per sample at each test volume per test strip lot). Results supported a minimum sample volume of 0.9 µL.

6. Temperature and humidity operating conditions were evaluated for temperatures 50°F and 104°F (10°C and 40°C) at relative humidity ranging from 10% to 90% R.H using an environmental stat chamber (thermal-stat and humidity-stat incubator). Three glucose concentration levels of approximately 70.0, 150.0 and 250.0 mg/dL as determined by YSI were tested. At each operating condition of temperature and humidity, each sample was tested with 6 meters and one test strip lot N=6). Results supported accurate performance of the device at temperature and humidity conditions of 50°F to 104°F and 10% to 95% RH.

7. The effect of altitude on the accuracy of the device was evaluated on the Premium Blood Glucose Monitoring System using a simulated hypobaric chamber. Venous blood samples at three glucose levels of approximately 83.0, 155.0 and 365.0 mg/dL (HCT within 43%), were used. The blood samples were tested in duplicate at two altitudes; sea level and 10500 feet, with five meters and one lot of test strips. Results supported the claim that the candidate device performs accurately up to an altitude of 10,000 feet.

8. The BeneCheck Premium Glu Monitoring System is intended for home use by single person and BeneCheck Premium PRO Glu Monitoring System intended for multi-patient use in a professional healthcare setting. Disinfection efficacy studies were performed on the materials comprising the meter demonstrating the efficacy of the chosen Super Sani-Cloth germicidal disposable wipes (EPA Reg. No. 9480-4) against hepatitis B virus using HBsAg testing. Robustness studies were also performed demonstrating that there was no change in performance or in the external materials of the meter after 12,000 cleaning and disinfection cycles. The robustness studies were designed to simulate three years of single-patient use and 3 years of multiple-patient use. Labeling has been reviewed for adequate instructions on the validated cleaning and disinfection procedures.

9. EMC testing was evaluated and certified by TUV Rheinland Taiwan Ltd. and a certificate of conformity was issued to General Life Biotechnology Co., Ltd on 02-07-2012.

10. The Premium meter was tested for its reliability to vibration testing. The meter performance and functions were not affected after the standard vibration tests.

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.