

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

A. 510(k) Number:

k052208

B. Purpose for Submission:

Premarket Notification 510(k) of intention to manufacture and market the Glucose Pilot Blood Glucose Monitoring System

C. Measurand:

Glucose

D. Type of Test:

Quantitative - Glucose Oxidase

E. Applicant:

Tianjin New Bay Bioresearch, Co. Ltd

F. Proprietary and Established Names:

Glucose Pilot Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1345, Glucose test system

21 CFR §862.1660, Quality control material (assayed and unassayed)

2. Classification:

Class II, I (reserved), respectively

3. Product code:

NBW, CGA, JJX

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Glucose Pilot Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from a fingerstick, for the lay-user. It is also intended for the professional use, which include fresh capillary whole blood. It is intended for use outside the body (in vitro diagnostics use) by diabetics at home and clinical settings as an aid to monitor the effectiveness of diabetes control.

3. Special conditions for use statement(s):

Not to be used for neonatal testing

4. Special instrument requirements:

Glucose Pilot Meter

I. Device Description:

The Glucose Pilot Blood Glucose Monitoring System consists of the Glucose Pilot meter, Glucose Pilot test strips, lancet device and control solutions and user manual. To measure blood glucose, the user inserts a test strip. A numerical code appears on the screen and the user compares this number to the number located on the test strip bottle to ensure the two numbers match. Once the user confirms that the code number in the meter matches the strip bottle, glucose testing can proceed. The user applies a blood drop from the fingerstick to the test strip. The meter initiates the test which completes in five seconds. Results are stored in the meters memory for tracking purposes.

J. Substantial Equivalence Information:

1. Predicate device name(s):

One Touch Ultra Glucose Monitoring System

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

k002134

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	To quantitatively measure glucose in fresh capillary whole blood	To quantitatively measure glucose in fresh capillary whole blood
Sample source	Capillary whole blood	Capillary whole blood
Measurement range	20-600 mg/dL	20-600 mg/dL
Test time	5 seconds	5 seconds

Differences		
Item	Device	Predicate
Operating temperature range	10-40°C	6-44°C
Operating Humidity range	25-90% Relative Humidity	10-90% Relative Humidity
Memory Capabilities	350 of the most recent blood test results. Does not store control results	150 blood glucose and control results
Power source	Two replaceable AAA size batteries	One replaceable 3.0v lithium battery

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

CLSI/NCCLS EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

L. Test Principle:

The Glucose Vision Meter measures the electronic current generated from the reaction of glucose with the chemical reagents impregnated into disposable electrode. Glucose in the blood sample reacts with glucose oxidase in the test strip, liberating electrons that produce a micro-current. The intensity of the current, as measured by the meter, correlates with the concentration of glucose in the sample. The measured current is electronically converted and displayed digitally on the meter's LCD as units of glucose in mg/dL (or mmol/L).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Repeatability (within run) was assessed by taking venous blood samples that were treated with EDTA and spiking these samples to generate 5 different levels of glucose concentration for the test. Each sample was measured 10 times by one operator on 10 different meters using one lot number in one day. Results are summarized below:

Samples	N	Mean mg/dL	SD	CV %
Level 1 30-50 mg/dL	100	45.4	4.3	9.5%
Level 2 51-110 mg/dL	100	94.5	4.4	4.6%
Level 3 111-150 mg/dL	100	147.4	4.5	3.0%
Level 4 151-250 mg/dL	100	247.1	4.6	1.9%
Level 5 251-400 mg/dl	100	372	8.9	2.4%

The sponsor prepared three control solutions of Low, Normal and High. Each of the controls was measured 10 times a day for 10 days using 10 meters and multiple operators. Results are summarized below:

Control Sample	N	Mean mg/dL	SD	CV %
Low	100	45.4	4.2	9.3%
Normal	100	119.5	4.3	3.6%
High	100	347.5	16.7	4.8%

b. Linearity/assay reportable range:

The linearity of the glucose measurements was demonstrated by comparing six prepared whole blood samples on the Glucose Vision meter and a glucose reference method. The six samples ranged in concentration from a low of approximately 22.7 mg/dL to a high of approximately 579 mg/dL. Linear regression of the comparison data yielded the following relationship:

$$\text{Glucose Vision} = (0.986 \times \text{Reference Method}) - 0.154 \text{ mg/dL}$$

$$r^2 = 0.9987$$

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

Two levels of control material are provided for use with the test system and are traceable to NIST and NBS standards. Values are assigned to the controls by comparing to a glucose reference method. The shelf life and in use stability were tested and verified.

d. *Detection limit:*

20-600 mg/dL

See linearity study above.

e. *Analytical specificity:*

Interference testing was conducted to determine the effect of select endogenous and exogenous substances. A summary of the data is presented below:

Chemical Compound	Reference Range (mg/dL)	Concentration showing no interference (mg/dL)
Acetaminophen (Tylenol)	1-2	5
Ascorbic Acid (Vitamin C)	0.8-1.2	10
Ephedrine	2	50
Ibuprofen	0.5-4.2	50
L-Dopa	0.3-10	5
Methyl Dopa	0.1-0.5	10
Dopamine	NA	10
Salicylate	15-30	50
Teracycline	0.4-4	2.5
Tolazamide	2.5	10
Tolbutamide	5.3-10	50
Endogenous Substances	Reference Range (mg/dL)	Concentration showing no interference (mg/dL)
Bilirubin	1.2	5
Cholesterol	<250	500
Creatinine	1.5	20
Hemoglobin	2.5	50
Triglyceride	<190	500
Uric Acid	7.0	10

The meter was tested at a higher altitude to assess the effect of low oxygen levels on the meters performance. No effect on performance was found when twenty five finger stick samples of different levels of blood were tested up to 11,967 ft. higher elevations were not tested. The sponsor presented data that supported using the test system between 10°C to 40°C.

Hematocrit Effect:

The effect of sample hemoglobin variation on the Glucose Pilot test system was tested experimentally by preparing samples of known hematocrit and spiking aliquots of these samples with three different levels of glucose. These samples were run on the Glucose Pilot and YSI; there was less than a $\pm 13\%$ bias across the claimed range of

30~55% Hematocrit.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

See clinical studies section below.

b. Matrix comparison:

Not applicable

3. Clinical studies:

The consumer study was performed at five POC sites with a total of 257 lay-users. The lay-users ranged in age, education and were equally divided between males and females; and equally divided between type-1 and type-2 diabetes, although not all participants have diabetes. Each participant performed their own fingerstick and tested their blood using the instructions in the User's guide. A trained professional then performed another fingerstick and tested the blood on the same meter. Blood was collected and measured on an YSI analyzer. The results are presented below.

a. Clinical Sensitivity:

Site	Number of samples	Glucose Pilot vs. YSI	R value	Sample Range (mg/dL)	% Clake Error Grid
Consumer Results					Zones A and B
1	40	$y = 0.8428x + 16.12$	0.889	64-323	97.5%
2	69	$y = 0.9555x + 7.9512$	0.966	67-617	100%
3	49	$y = 1.032x - 4.5124$	0.997	117-520	100%
4	50	$y = 1.0332x - 2.0525$	0.992	119-583	100%
5	49	$y = 0.9739x + 8.501$	0.994	112-422	100%
Sum	257	$y = 01.0095x + 0.0358$	0.984	64-617	99.6%
Professional Results					
1	40	$y = 0.8840x + 12.98$.911	64-323	100%
2	69	$y = 0.9343x + 12.99$.975	67-617	100%
3	49	$y = 0.9693x + 13.728$.991	117-520	100%
4	50	$y = 0.9963x + 11.885$.989	119-583	100%
5	49	$y = 0.9799x + 6.613$.989	112-422	100%
Sum	257	$y = 0.989x + 6.2598$.984	64-617	100%

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The normal fasting adult glucose range for a non-diabetic is 70 -110 mg/dL. One-hour after a meal, normal blood glucose results should be less the 160 mg/dL. A medical professional should determine the range that is appropriate for diabetes patients.

N. Instrument Name:

Glucose Pilot Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

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

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 fingertip. For capillary whole blood, since the sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

Each bottle of test strips as a code number which is used to calibrate the meter. The user confirms that the code number on the test strip bottle matches the code number in the instrument. If they are different then the user changes the number by depressing the S button on the meter until the correct number is displayed. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing a high and low glucose control solution with this device. To mark the test result as a control the user, after the units of measure is displayed is instructed to press and hold the S button until CTL appears on the display. This prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. If control results fall outside these ranges, the user is referred to a list of troubleshooting steps and the customer care line.

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.