

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

A. 510(k) Number:

k080636

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Whole blood glucose concentration through a quantitative amperometric assay
(Glucose Oxidase)

E. Applicant:

HuBDIC Co., Ltd.

F. Proprietary and Established Names:

Duo-Max Blood Pressure and Glucose Monitor, Model HMF-100

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345, Glucose Test System

21 CFR § 870.1130, Noninvasive Blood Pressure Measurement System

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

2. Classification:

Class II

Class I (reserved)

3. Product code:

NBW, CGA, JJX

DXN

4. Panel:

75 (Clinical Chemistry)

74 (Cardiovascular)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Blood pressure and glucose monitor, Duo-Max™ consists of a meter with wrist cuff and glucose test strips. The glucose test system is intended for use in the quantitative measurement of glucose in capillary whole blood taken from the fingertip, dorsal hand, ventral palm, upper arm, forearm, calf and thigh. Glucose testing is done outside the body (In Vitro diabetes mellitus, or in clinical settings by healthcare professionals. Glucose testing system is not to be used for the diagnosis or screening of diabetes. It is not intended for use on neonates. Also the blood pressure test system measures systolic and diastolic blood pressure and pulse rate from adult's wrist in the home care environment. The device employs a wrist cuff and the oscillometric metric method of measurement.

3. Special conditions for use statement(s):
 - Not for use on critically ill patients, dehydrated patients or hyperosmolar patients
 - Not for neonatal use
 - Not for screening or diagnosis of diabetes mellitus
 - Alternative site testing is for use at times of steady state only
4. Special instrument requirements:
Duo-Max Blood Pressure and Glucose Monitor, Model HMF-100

I. Device Description:

HuBDIC's Duo- Max Blood Pressure and Glucose Monitor System, Model HMF-100 combines the function of a blood pressure meter and a blood glucose monitoring system in one unit. Supplies with the meter are test strips, lancets, Lancing device, storage case, batteries and log book.

HMF-100 adopts the wrist type cuff for blood pressure monitoring. The cuff and control unit are combined into a single wrist-mounted assembly. The user interface pane has power switch, timer switch, memory switch and LCD for displaying the systolic and diastolic blood pressure, pulse rate, date and time. This device has the memory function that permits memory and display of the 180 most recent measurement results.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Blood Glucose and Blood Pressure Monitor System, Model BGP-100 Sein
Electronics Co., Ltd
Infopia Glucolab™ Blood Glucose Monitoring System
2. Predicate 510(k) number(s):
k052108
k051285
3. Comparison with predicate:

Similarities		
Item	Device	Predicate (k052108)
Detection method	Amperometry	Amperometry
Enzyme	Glucose oxidase (Aspergillus niger)	Glucose oxidase (Aspergillus niger)
Test range	20-600 mg/dL	30-550 mg/dL
Hematocrit range	30-55%	30-55%
Sample volume	1 µL	1 µL
Glucose test time	5 seconds	5 seconds

Differences		
Item	Device	Predicate
Pulse Rate	20 ~ 199 pulse/min	40 ~ 199 pulse/min
Number of readings stored in memory	180 (Blood Pressure) 270 (Blood Glucose)	60 (Blood Pressure) 150 (Blood Glucose)
Size L x W x H (mm)	64(W) x 84(W) x 31(H)(mm)	62(W) x 83(W) x 33(H)(mm)
Weight	163g	192g

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

- CLSI EP7-A, Interference Testing in Clinical Chemistry; Proposed Guideline
- ISO 15197:2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Test Systems for Self Managing Diabetes Mellitus
- AAMI SP10:2002, Manual, Electronic or Automated Sphygmomanometers

L. Test Principle:

Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, and the current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

Blood pressure: the pressure sensor in the cuff detects small changes in pressure and converts them to electrical signals. The meter analyzes the signals and converts them to standard measurements of pulse rate and systolic and diastolic blood pressure.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-Run

The testing was conducted using venous blood, collected in a heparin blood collection tube. Glucose was added to the blood to prepare 5 different levels of glucose for the testing. The glucose concentration ranges

were: 30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, and 251-400 mg/dL. For each testing range, the samples were tested 50 times.

Range (mg/dL)	Assays	Mean (mg/dL)	SD (mg/dL)	CV (%)
30~50	50	43.7	1.8	4.2
51~110	50	86.8	2.4	2.8
111~150	50	138.4	4.1	3.0
151~250	50	215.9	5.9	2.8
251~400	50	373.6	10.7	2.9

Day-to-Day Precision

Three control solutions of Low, Normal and High were prepared. Each control was tested four times a day, twice in the morning and twice in the afternoon for 20 days.

Control solution	N	mean (mg/dL)	SD (mg/dL)	CV (%)
Low	80	50.5	1.0	2.1
Normal	80	106.6	1.9	1.7
High	80	306.3	2.9	1.0

b. Linearity/assay reportable range:

To establish the linearity of the system through the range of 20 to 600 mg/dL, 11 glucose adjusted whole blood samples across the range were tested on the meter and compared to the YSI 2300 using 5 replicate measurements. Linear regression yields the following statistics:

Slope	1.0031
Y-intercept	0.1625
R^2	0.9999

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

The sponsor claims that the device is traceable to a laboratory analyzer which is calibrated to a NIST traceable glucose standard.

The two control solutions (normal and high levels) consist of buffered aqueous solutions of β -D-glucose and non-reactive ingredients. Lot-specific ranges are printed on the test strip bottle label.

Closed Vial Stability of Control Solution: The measured glucose levels of 3 lots of each level of control solution were tested using a real-time stability study. The results showed that during the tested time frame of 847 days at room temperature, the controls were within the specified ranges. The sponsor

claims a closed vial stability of 26 months.

Opened Vial Stability of Control Solution: The measured glucose levels of 3 lots of each level of control solution were tested during 96 days and were found to be within the specified ranges. The sponsor claims an open vial stability of 90 days.

d. *Detection limit:*

The measuring range of the system is 20 - 600 mg/dL. See the linearity study above (section M.1.b.).

e. *Analytical specificity:*

Spiked whole blood samples containing three levels of glucose, with and without interfering substances, were prepared to test common endogenous and exogenous substances for interference. Levels tested for each interferant (in mg/dL) are summarized below:

Low glucose sample < (60mg/dL)

Interference substance	Highest interference Level Tested (mg/dL)	Mean of Test Results		(mg/dL) Difference
		Glucose Level With No Interferant (mg/dL)	Glucose Level With Interferant Added (mg/dL)	
Acetaminophen	<u>20</u>	45.0	43.4	<u>-1.6</u>
Bilirubin	<u>40</u>	52.4	46.4	<u>-6.0</u>
Gentistic acid	<u>50</u>	45.0	52.0	<u>7.0</u>
Uric acid	<u>20</u>	52.4	49.2	<u>-3.2</u>
Levo-Dopa	<u>4</u>	47.6	46.0	<u>-1.6</u>
Creatinine	<u>30</u>	45.0	44.2	<u>-0.8</u>
Methyl-Dopa	<u>2.5</u>	47.6	49.2	<u>1.6</u>
Tolazamide	<u>5</u>	52.4	51.2	<u>-1.2</u>
Dopamine	<u>13</u>	45.0	46.4	<u>1.4</u>
Ascorbate	<u>3</u>	45.0	48.0	<u>3.0</u>
EDTA	<u>640</u>	45.0	49.8	<u>4.8</u>
Glutathione	<u>1</u>	45.0	42.8	<u>-2.2</u>
Heparin	<u>1,000</u>	45.0	43.2	<u>-1.8</u>
Ibuprofen	<u>40</u>	52.6	48.4	<u>-4.2</u>
Salicylic acid	<u>50</u>	45.0	44.2	<u>-0.8</u>

Tetracycline	<u>0.4</u>	45.0	44.8	<u>-0.2</u>
Tolbutamide	<u>100</u>	52.6	52.0	<u>-0.6</u>
Urea	<u>500</u>	45.0	53.0	<u>8.0</u>
Cholesterol	<u>500</u>	45.8	51.6	<u>5.8</u>
TG	<u>3000</u>	51.4	56.8	<u>5.4</u>
Galactose	<u>50</u>	45.0	42.0	<u>-3.0</u>
Xylose	<u>10</u>	45.0	43.6	<u>-1.4</u>
Maltose	<u>300</u>	45.0	41.2	<u>-3.8</u>

Mid-level glucose sample (170mg/dL)

Interference substance	Highest interference Level Tested (mg/dL)	Mean of Test Results		(% Difference)
		Glucose Level With No Interferant (mg/dL)	Glucose Level With Interferant Added (mg/dL)	
Acetaminophen	<u>20</u>	171.0	168.6	<u>-1.4</u>
Bilirubin	<u>40</u>	166.2	157.2	<u>-5.4</u>
Gentistic acid	<u>50</u>	171.0	181.6	<u>6.2</u>
Uric acid	<u>20</u>	166.2	161.6	<u>-2.8</u>
Levo-Dopa	<u>4</u>	167.6	164.6	<u>-1.8</u>
Creatinine	<u>30</u>	171.0	168.8	<u>-1.3</u>
Methyl-Dopa	<u>2.5</u>	167.6	171.2	<u>2.1</u>
Tolazamide	<u>5</u>	166.2	163.4	<u>-1.7</u>
Dopamine	<u>13</u>	171.0	172.8	<u>1.1</u>
Ascorbate	<u>3</u>	171.0	175.2	<u>2.5</u>
EDTA	<u>640</u>	171.0	178.2	<u>4.2</u>
Glutathione	<u>1</u>	171.0	167.4	<u>-2.1</u>
Heparin	<u>1,000</u>	171.0	167.4	<u>-2.1</u>
Ibuprofen	<u>40</u>	169.2	162.8	<u>-3.8</u>
Salicylic acid	<u>50</u>	171.0	168.4	<u>-1.5</u>
Tetracycline	<u>0.4</u>	171.0	169.4	<u>-0.9</u>
Tolbutamide	<u>100</u>	169.2	167.4	<u>-1.1</u>
Urea	<u>500</u>	171.0	184.2	<u>7.7</u>
Cholesterol	<u>500</u>	171.0	179.8	<u>5.1</u>
TG	<u>3000</u>	169.6	179.2	<u>5.7</u>
Galactose	<u>50</u>	171.0	166.6	<u>-2.6</u>

Xylose	<u>10</u>	171.0	168.6	<u>-1.4</u>
Maltose	<u>300</u>	171.0	166.2	<u>-2.8</u>

High glucose sample > (240mg/dL)

Interference substance	Highest interference Level Tested (mg/dL)	Mean of Test Results		(% Difference)
		Glucose Level With No Interferant (mg/dL)	Glucose Level With Interferant Added (mg/dL)	
Acetaminophen	<u>20</u>	290.2	285.6	<u>-1.6</u>
Bilirubin	<u>40</u>	289.4	273.0	<u>-5.7</u>
Gentistic acid	<u>50</u>	290.2	308.8	<u>6.4</u>
Uric acid	<u>20</u>	289.4	281.8	<u>-2.6</u>
Levo-Dopa	<u>4</u>	291.0	284.6	<u>-2.2</u>
Creatinine	<u>30</u>	290.2	286.0	<u>-1.4</u>
Methyl-Dopa	<u>2.5</u>	291.0	296.4	<u>1.9</u>
Tolazamide	<u>5</u>	289.4	284.8	<u>-1.6</u>
Dopamine	<u>13</u>	290.2	293.0	<u>1.0</u>
Ascorbate	<u>3</u>	290.2	297.0	<u>2.3</u>
EDTA	<u>640</u>	290.2	301.8	<u>4.0</u>
Glutathione	<u>1</u>	290.2	284.4	<u>-2.0</u>
Heparin	<u>1,000</u>	290.2	283.2	<u>-2.4</u>
Ibuprofen	<u>40</u>	289.4	278.6	<u>-3.7</u>
Salicylic acid	<u>50</u>	290.2	286.4	<u>-1.3</u>
Tetracycline	<u>0.4</u>	290.2	288.6	<u>-0.6</u>
Tolbutamide	<u>100</u>	289.4	286.8	<u>-0.9</u>
Urea	<u>500</u>	290.2	313.2	<u>7.9</u>
Cholesterol	<u>500</u>	288.8	304.4	<u>5.4</u>
TG	<u>3000</u>	291.0	307.4	<u>5.6</u>
Galactose	<u>50</u>	290.2	281.8	<u>-2.9</u>
Xylose	<u>10</u>	290.2	284.8	<u>-1.9</u>
Maltose	<u>300</u>	290.2	281.0	<u>-3.2</u>

Interference testing showed that the system results in less than $\pm 10\%$ bias (or ± 10 mg/dL for glucose samples less than 60 mg/dL) in the presence of high concentrations of interferants, even beyond clinically significant ranges.

An altitude study was performed with 9 venous blood samples ranging from 30 to 530 mg/dL. Testing was performed at altitudes of sea level and 10,000 feet (using a chamber). The test data showed that the bias versus YSI at 10,000 feet is the same bias versus YSI observed at sea level. These data indicate no additional effect due to altitude up to the claimed altitude of 10,000 feet.

Hematocrit interference was evaluated by adjusting the glucose concentrations and hematocrit levels of venous blood samples. The venous blood samples were spiked to 8 glucose concentrations (40, 70, 110, 180, 250, 350, 450, and 550 mg/dL). The hematocrit levels were adjusted to 30%, 40%, 55%. Each sample was assayed 15 times and the maximum percent bias was calculated compared to the 40% hematocrit samples. The sponsor demonstrated that the bias did not exceed ± 15 mg/dL when glucose concentration is ≤ 75 mg/dL and bias did not exceed $\pm 15\%$ when glucose concentration is > 75 mg/dL for hematocrit concentrations within the claimed range of 30% to 55%.

- f. *Assay cut-off:*
Not Applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

To demonstrate the accuracy performance of the Duo-Max Blood Pressure and Glucose Monitor, 160 patients samples were tested in duplicate using capillary blood samples from the finger (with samples ranging from 31 to 487 mg/dL) and compared to the results from a laboratory reference method using samples taken at the same time. Samples with blood glucose levels below 50 mg/dL were obtained by glycolysis of patient samples and samples above 400 were obtained by supplementing the samples with glucose. Results are summarized below:

	Fingerstick vs. Reference
Samples < 75 mg/dL within ± 15 mg/dL YSI	60/60 (100%)
Samples ≥ 75 mg/dL within $\pm 20\%$ YSI	258/260 (99%)
Total	318/320 (99%)

A consumer study was performed with 150 lay-users and a technician to see how well results obtained from a lay user compared to results obtained by a technician. The labeling provided to the users was in English only. Each participant performed their own test and tested their blood using the instructions in the user's manual, then a technician performed a test using the same meter. Samples ranged from 50 - 537 mg/dL. Results are summarized below:

	Lay User Fingerstick vs. Technician Fingerstick
Samples < 75 mg/dL within ±15 mg/dL YSI	25/25 (100%)
Samples ≥ 75 mg/dL within ± 20% YSI	124/125 (99%)
Total	149/150 (99%)

A study was performed with 100 participants to determine if the performance of the Duo-Max on alternate site (palm, forearm, thigh, and calf) were comparable to fingertip when obtained by lay users). The labeling provided to the users was in English only. Each participant performed their own test and tested their blood using the instructions in the user’s manual. Samples ranged from 61 - 485 mg/dL. Results are summarized below:

	Dorsal Palm vs. Fingerstick	Ventral Palm vs. Fingerstick	Forearm vs. Fingerstick	Upper Arm vs. Fingerstick	Calf vs. Fingerstick	Thigh vs. Fingerstick
Samples < 75 mg/dL within ±15 mg/dL Fingerstick	6/6 (100%)	6/6 (100%)	6/6 (100%)	7/7 (100%)	6/6 (100%)	8/8 (100%)
Samples ≥ 75 mg/dL within ± 20% Fingerstick	93/94 (99%)	93/94 (99%)	93/94 (99%)	92/93 (99%)	93/94 (99%)	91/92 (99%)
Total	99/100 (99%)	99/100 (99%)	99/100 (99%)	99/100 (99%)	99/100 (99%)	99/100 (99%)

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated matrix.

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):

The sponsor provided a readability study that indicated that the user manual, test strip labeling, and control solution labeling is at an 8th grade reading level or below.

4. Clinical cut-off:
Not Applicable.

5. Expected values/Reference range:

The sponsor included the following expected values for normal glucose levels for people without diabetes in their strip labeling:

70 mg/dL (3.9 mmol/L) - 110 mg/dL (6.1 mmol/L)¹

Two hours after meals: less than 140 mg/dL (7.8 mmol/L)²

¹Stedmans Medical Dictionary, 27th Edition, 1999, p 755.

²American Diabetes Association Clinical Practice Recommendations 2004, Diabetes Care, Vol. 27 Supplement 1, p. S9

N. Instrument Name:

Duo-Max Blood Pressure and Glucose Monitor, Model HMF-100

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 _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission:

Yes _____ or No _____

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes _____ 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, and forearm. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A code number is provided with each batch of test strips to calibrate the meter for

that lot. The code number is associated with the meter by inserting a test strip and entering the code number to match that found on the test strip bottle. No further calibrations are required of the user.

6. Quality Control:

The sponsor has two levels of controls available for this meter with one level coming with the kit. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is referred to a troubleshooting section at the end of the control test instructions of the owner's manual to identify possible reasons control results fall outside these ranges.

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

The blood pressure monitoring system was reviewed by the Office of Device Evaluation and found to be acceptable.

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.