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

A. 510(k) Number:

k113636

B. Purpose for Submission:

New Device

C. Measurand:

Capillary Whole Blood Glucose

D. Type of Test:

Quantitative, glucose oxidase

E. Applicant:

Philosys Co Ltd

F. Proprietary and Established Names:

Gmate VOICE™ Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345, Blood Glucose Test System, Glucose Oxidase

   21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:

   Blood Glucose Test System, Class II

   Quality Control Material, Class I, reserved

3. Product code:

   CGA, Glucose Oxidase, Glucose

NBW- System, Test, Blood Glucose, Over the Counter
JJX - Single Analyte Controls (assayed and unassayed)

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below.

2. Indication(s) for use:

   The Gmate® VOICE™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, hand, upper arm, forearm, calf or thigh as an aid in monitoring the effectiveness of diabetes management in the home by individuals with diabetes. The Gmate® VOICE™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared with any other person.

   The Gmate® VOICE™ Blood Glucose Monitoring System is for self testing outside the body (in vitro diagnostic use only) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Gmate® VOICE™ Blood Glucose Monitoring System should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

   The Gmate® VOICE Blood Glucose Monitoring System includes a speaking feature that provides audible test results for diabetic users.

   The Gmate® Blood Glucose Test Strips are for use with the Gmate® VOICE™ Blood Glucose Monitoring System for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, hand, upper arm, forearm, calf or thigh.

   The Gmate® Control Solution is for use with the Gmate® VOICE Blood Glucose Monitoring System and is intended as a quality control measure to verify the accuracy of your blood glucose test results and to ensure that the Gmate® VOICE meter and Gmate® Test Strips are working properly. The Gmate® Control Solution is intended for use by people with diabetes at home.

3. Special conditions for use statement(s):

   For prescription and over-the-counter use.

Not for neonatal use, not for screening or diagnosis of diabetes mellitus.

Not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients.

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

AST testing should only be done during steady-state times (when glucose is not changing rapidly).

Only use fresh capillary whole blood. Do not use serum or plasma

4. Special instrument requirements:

I. Device Description:

The Gmate VOICE™ Blood Glucose Monitoring System measures glucose concentration in human blood. The Gmate VOICE™ Blood Glucose Monitor should be used with the Gmate Blood Glucose Test Strips The Gmate VOICE Blood Glucose Monitoring System consists of the following components:

- Gmate VOICE Meter
- Gmate Blood Glucose Test Strips
- Lancing Device
- Lancets
- Carrying Case
- A clear AST cap is used for obtaining a blood drop with lancing device and is available separately

The Gmate Control Solutions are aqueous materials that are available separately at three levels. Level 1 is a low level and contains 0.05% by weight glucose (approximately 50 ±15 mg/dL); level 2 is a medium level and contains 0.1% by weight glucose (approximately 100 ±15 mg/dL); and level 3 is a high level and contains 0.3% by weight glucose (approximately 300 ±45 mg/dL).

The Gmate® VOICE Blood Glucose Monitoring System includes a speaking feature that provides audible test results for diabetic users.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   OneTouch® ULTRA® System

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

k002134

3. Comparison with predicate:

Similarities and Differences		
Item	Candidate Device: Gmate VOICE (k113636)	Predicate Device: ONE TOUCH Ultra (k002134)
Intended Use		Same
Detection Method	Amperometry, current is generated by oxidation of reduced mediator	Same
Enzyme	Glucose Oxidase	Same
Mediator	Potassium ferricyanide	Same
Electrode	Carbon electrode	Same
Test Range	20-600 mg/dL	Same
Hematocrit Range	20-60%	30-55%
Test Time	5 seconds	Same
Sample Volume	0.5 μL	1 μL
Temperature & Humidity Range	10-40°C 10-90%	6-44°C 10-90%
Open use Time	3 Months	Same

Similarities and Differences		
Item	Candidate Device: Gmate VOICE (k113636)	Predicate Device: ONE TOUCH Ultra (k002134)
Coding	No Coding	Button (C1-C49)
Memory Capability	7, 14, 30-day average and last 500 tests in the memory	14, 30 day average and last 150 tests in the memory
Power	Two 1.5V alkaline batteries	3V Li Battery (C2032)
Battery Life	Running 1000 tests	Same
Size: L x W x H (mm)	88.0 x 56.0 x 29.6	80 x 57 x 21
Weight	77.7g (with batteries)	42g (with battery)
Warranty	5 years	3 years
Software	Gmate™ Diabetes Management Software	ONETOUCH® diabetes Management Software

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

ISO 15197: 2003 In Vitro diagnostic test systems requirements for blood glucose monitoring system for self testing in managing

CLSI EP05-A2: 2004 Evaluation of precision performance of quantitative measurement methods; Approved guideline

CLSI EP06-A: 2005 Evaluation of Linearity Quantitative Analytical Method; Proposed guideline

CLSI EP07-A2: 2005 Interference Testing in Clinical Chemistry; Approved guideline

CLSI EP09-A2-IR: 2002 Method Comparison and Bias Estimation Using Patient Samples; Approved guideline

CEN 13640 Stability testing of in vitro diagnostic medical device

L. Test Principle:

The Gmate™ VOICE system is based on measurement of a small electrical current produced by the reaction of glucose in the blood sample with the reagents on the Gmate™ blood glucose test strip. This current changes with the amount of glucose in the blood sample. The glucose concentration in the sample is calculated based on the electrical current and displayed on the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Repeatability (between run precision) was evaluated at room temperature using venous whole blood adjusted to five different levels of glucose with D-(+) Glucose in Phosphate Buffer 7.4. Operator-to-operator precision was studied by having two operators measure each sample fifty times. The results are as follows.

[Glucose] (mg/dL)	Statistic	Operator
30-50	Mean	41.8
	SD	1.8
	CV %	4.2
51-110	Mean	100.3
	SD	1.5
	CV %	2.5
111-150	Mean	132.2
	SD	3.0
	CV %	2.3
151-250	Mean	230.1
	SD	4.3
	CV %	2.3
251-400	Mean	374.3
	SD	11.1
	CV %	3.0

Meter-to-Meter precision was evaluated by taking ten measurements using each of ten individual Gmate Voice blood glucose meters for each glucose concentration. The results are as follows:

[Glucose] (mg/dL)	Meter	1	2	3	4	5	6	7	8	9	10
30-50	Mean	42	42	42	42	42	42	42	43	42	42
	SD	1.0	1.2	1.2	1.3	1.0	1.5	0.9	1.8	1.2	1.3
	CV %	2.4	2.8	2.8	3.1	2.4	3.6	2.2	4.3	2.7	3.1
51-110	Mean	101	100	101	101	100	101	100	101	100	100
	SD	3.3	3.3	3.4	2.8	3.3	2.5	2.7	2.7	2.3	2.3
	CV %	3.2	3.3	3.4	2.8	3.3	2.5	2.7	2.7	2.3	2.3
111-150	Mean	132	132	132	133	133	133	132	132	132	133
	SD	2.3	3.2	1.9	3.7	3.6	3.6	2.8	2.7	2.4	3.1
	CV %	1.8	2.4	1.4	2.7	2.7	2.7	2.1	2.1	1.8	2.3
151-250	Mean	230	233	231	234	232	231	231	232	232	233
	SD	4.8	4.2	3.2	4.0	5.2	3.6	4.6	5.8	4.4	3.7
	CV %	2.1	1.8	1.4	1.7	2.2	1.5	2.0	2.5	1.9	1.6
251-400	Mean	378	376	377	377	375	378	370	373	370	370
	SD	9.4	10.6	12.4	12.5	7.5	10.1	8.9	8.7	8.0	8.5
	CV %	2.5	2.8	3.3	3.3	2.0	2.7	2.4	2.3	2.2	2.3

Intermediate (day-to-day) precision of the Gmate Voice BGMS was determined using glucose test strips and control solution at three different glucose concentration levels. Data was collected over a period of twenty days by performing two runs per day. The data is summarized below.

Level 1 (35-65 mg/dL)			Level 2 (75-125 mg/dL)			Level 3 (225-375 mg/dL)		
Mean (mg/dL)	SD (mg/dL)	CV (%)	Mean (mg/dL)	SD (mg/dL)	CV (%)	Mean (mg/dL)	SD (mg/dL)	CV (%)
41	0.8	1.9	101.8	1.9	1.8	308.9	3.7	1.2

A second day-to-day study was performed by collecting data over a period of ten days on ten individual Gmate Voice blood glucose meters. The data is summarized below.

	Level 1 (35-65 mg/dL)			Level 2 (75-125 mg/dL)			Level 3 (225-375 mg/dL)		
Meter	Mean (mg/dL)	SD (mg/dL)	CV (%)	Mean (mg/dL)	SD (mg/dL)	CV (%)	Mean (mg/dL)	SD (mg/dL)	CV (%)
1	41	0.7	1.6	103	3.1	3.0	292	7.3	2.5
2	41	0.9	2.1	102	2.6	2.5	295	9.1	3.1
3	41	0.8	2.0	103	2.5	2.4	295	9.1	3.1
4	41	0.9	2.1	102	2.1	2.1	296	9.3	3.2
5	41	0.8	2.0	104	3.2	3.1	295	9.7	3.3
6	41	0.8	2.1	105	2.0	1.9	295	8.6	2.9
7	41	1.1	2.6	103	1.7	1.7	299	8.6	2.9
8	41	0.6	1.6	105	2.2	2.1	294	8.2	2.8
9	41	1.0	2.4	103	2.2	2.1	292	6.5	2.2
10	41	0.9	2.1	104	2.5	2.5	295	10.3	3.5

b. Linearity/assay reportable range:

A 50 mL venous blood sample was taken and treated with EDTA. Known volumes of low and high glucose concentration pools were mixed to prepare 14 samples with a range of glucose concentration ranging from 7 to 634 mg/dL. Glucose levels were determined by the YSI 2300 glucose analyzer. This was performed using three different strip lots. Each glucose level was measured 5 times using the Gmate Voice blood glucose meters and compared with those obtained from YSI-2300. A plot of Gmate Voice data versus YSI reference data was constructed and linear regression analysis was performed on the data. The device was determined to be linear with the following results:

Test Strip Lot	Slope	Intercept	R^2
1	1.001	1.121	0.999
2	1.000	0.773	0.999
3	1.002	0.456	0.999

The claimed measuring range of the device is 20-600 mg/dL

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

Traceability

The reference instrument used is the YSI 2300 Glucose analyzer and is calibrated by YSI 2747 Glucose Standard which is a NIST traceable glucose standard. The controls are prepared at two target concentrations gravimetrically and the glucose concentrations are verified with the YSI reference method.

The primary calibrator is traceable to NIST SRM 917b.

Stability

Three lots of Gmate Control solutions were stored at room temperature for 112 days and were tested using one strip lot periodically and compared to the results on a YSI analyzer and at time zero. All three lots of control solution passed the acceptance criteria and the shelf life of the Gmate Control solutions was determined to be 3 months when stored in a cool, dry place out of sunlight at 4-30°C. For in-use stability, three lots of Gmate Control solutions were stored at room temperature for three months and three strip lots were used to test each control solution for in-use stability. All three lots of the control solutions met the acceptance criteria and the control solutions should be stored at 4-30° and expire three months after opening the control solution vial.

Three lots of test strips were stored between 2-40°C for 750 days and were tested using three control solution lots and compared to the results at time zero. The results indicate a two year shelf-life for the test strips when stored at 2-32°C in a cool, dry place out of sunlight. Three lots of strips were tested with three lots of control solutions at room temperature for three months to evaluate the in-use stability of the test strips. All three lots of test strips met the acceptance criteria and the test strips should be stored at 2-32°C in a cool, dry place out of sunlight and expire three months after opening the test strip vial.

Value Assignment

The glucose control solutions are supplied with the test system to validate the performance of the meter. The control solutions are at two glucose concentrations: 100 mg/dL and 300 mg/dL, and are supplied as ready to use liquids. Targeted concentrations are prepared gravimetrically. The control solution is tested 100 times with each strip lot and the average is listed as the control range on the test strip vial label.

Control Solution	Target Concentration	Acceptable Concentration Range assayed by
Level 1	50 mg/dL	Average ± 15 mg/dL
Level 2	100	Average ± 20 %
Level 3	300	Average ± 15 %

d. Detection limit:

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

e. Analytical specificity:

An interference study was performed by spiking venous whole blood from an individual with endogenous and exogenous interfering substances. Five concentrations of each interferent were tested at two blood glucose concentrations on three lots of strips. The bias was defined as (glucose value of sample with interferent - glucose value of sample without interferent) / glucose value of sample without interference. The bias of all samples tested was within ± 10% between the test and the control groups. The sponsor claims no significant interference (≤ 10% difference) for the substances and concentrations shown below.

Interferent	Concentration (mg/dL)
Acetaminophen	20
Bilirubin	40
Ascorbate	3
Uric Acid	20

Maltose	20
Xylose	20
Galactose	20
Urea	500
Levo-Dopa	4
Methyl-Dopa	2.5
Dopamine	13
Salicylic acid	50
Ibuprofen	40
Tolbutamide	100
Cholesterol	500
Caffeine	50
Fructose	50
Lactose	50
Lipoic acid	50
Triglyceride	3000
Sucrose	50
Hemoglobin	20 g/dL

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy:
To assess system accuracy, the Gmate VOICE Blood Glucose Monitoring System was compared to a YSI 2300 STAT laboratory instrument. Capillary blood samples were collected in a capillary EDTA tube. To obtain samples below 50 mg/dL, the sample was incubated to allow glucose to hydrolyze and adjust to human temperature. To obtain samples above 400 mg/dL, the blood was supplemented with glucose and then incubated to human temperature. One hundred samples were collected at a clinical center from diabetic patients throughout one week. Samples between 33-442 mg/dL were tested in the accuracy study. Linear regression based on single glucose measurements produced the following: $y = 0.9978x - 2.1025$, $R^2 = 0.9905$.The system accuracy is shown below.

[Glucose]	Within± 5 mg/dL Within± 5 %	Within± 10 mg/dL Within± 10 %	Within± 15 mg/dL Within± 15 %	Within± 20 mg/dL Within± 20 %
<75 mg/dL	4/15 (27%)	14/15 (93.3%)	15/15 (100%)	15/15 (100%)
≥75 mg/dL	50/85 (58%)	81/85 (95%)	85/85 (99%)	85/85 (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):

User results with capillary blood from the fingertip
A user performance study was performed to compare the lay user self-test results to the YSI 2300 reference method. The study was performed at 1 clinical site with samples from 102 subjects using three lots of test strips. The samples tested ranged from 64- 473 mg/dL. Each subject was asked to read the English version of the draft label package, which will be provided to users when the device is marketed. Lay users obtained and tested their fingerstick capillary whole blood samples using the Gmate VOICE system and auto disabling lancing devices. Control tests were then performed by healthcare professionals using the same meter. Linear regression analyses results based on single glucose measurements are summarized below.

Comparison	Slope	Intercept	R^2
YSI vs. Lay User	0.9978	-2.1025	0.9905

Lay user results vs. YSI are summarized below.

[Glucose]	**Within± 5 mg/dL Within± 5 %**	**Within± 10 mg/dL Within± 10 %**	**Within± 15 mg/dL Within± 15 %**	**Within± 20 mg/dL Within± 20 %**
<75 mg/dL	4/15 (27%)	14/15 (93%)	15/15 (100%)	15/15 (100%)
≥75 mg/dL	50/85 (59%)	81/85 (95%)	85/85 (100%)	85/85 (100%)

User results with capillary blood from alternative sites

A user performance study was performed to compare the lay user self-test results to the YSI 2300 reference method. The study was performed at one clinical site. 102 subjects collected capillary blood from the fingertip, upper arm, forearm, hand, thigh, and calf. Each subject was asked to read the English version of the draft labeling, which will be provided to users when the device is marketed.

Linear regression analysis results are summarized below.

Comparison	Slope	Intercept	R^2
YSI vs. fingertip	1.0051	-4.3677	0.9921
YSI vs. Upper arm	0.9919	-0.8426	0.9906
YSI vs. Forearm	0.9825	-0.7819	0.9902

YSI vs. Hand	0.9824	-5.7565	0.9928
YSI vs. Thigh	1.0182	-6.8072	0.9921
YSI vs. Calf	0.9875	-1.4224	0.9911

User accuracy results are summarized below.

[Glucose]	**Within± 5 mg/dL Within± 5 %**	**Within± 10 mg/dL Within± 10 %**	**Within± 15 mg/dL Within± 15 %**	**Within± 20 mg/dL Within± 20 %**
YSI vs. Fingertip				
<75 mg/dL	7/8 (88%)	8/8 (100%)	8/8 (100%)	8/8 (100%)
≥75 mg/dL	65/94 (69%)	88/94 (94%)	94/94 (100%)	94/94 (100%)
YSI vs. Upper Arm				
<75 mg/dL	5/8 (62.5%)	8/8 (100%)	8/8 (100%)	8/8 (100%)
≥75 mg/dL	61/94 (65%)	88/94 (94%)	94/94 (100%)	94/94 (100%)
YSI vs. Forearm				
<75 mg/dL	7/8 (93.8%)	8/8(100%)	8/8 (100%)	8/8 (100%)
≥75 mg/dL	55/94 (59%)	86/94 (92%)	93/94 (99%)	94/94 (100%)
YSI vs. Hand				
<75 mg/dL	3/8 (37.5%)	6/8 (75%)	8/8 (100%)	8/8 (100%)
≥75 mg/dL	44/94 (47%)	79/94 (85%)	93/94 (99%)	94/94 (100%)
YSI vs. Thigh				

<75 mg/dL	7/8 (88%)	8/8 (100%)	8/8 (100%)	8/8 (100%)
≥75 mg/dL	57/94 (61%)	86/94 (91%)	92/94 (98%)	94/94 (100%)
YSI vs. Calf				
<75 mg/dL	4/8 (50%)	8/8 (100%)	8/8 (100%)	8/8 (100%)
≥75 mg/dL	62/94 (66%)	85/94 (91%)	92/94 (98%)	94/94 (100%)

4. Clinical cut-off**:**

   Not Applicable

5. Expected values/Reference range:

   Expected blood glucose results for non-pregnant people without diabetes were cited from the literature[1] and presented in the labeling as follows:

   Fasting: 70-99 mg/dL

   [1]American Diabetes Association, Position Statement, Standards of Medical Care in Diabetes, Diabetes Care 34 (suppl1): S11-S61, 2011.

N. Instrument Name:

Gmate VOICE Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.5 µL.

   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 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, thigh, hand, calf, forearm, and upper arm only. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   There is no calibration required for the Gmate™ VOICE blood glucose meter by the user.

6. Quality Control:

   Glucose control solutions at three different concentrations can be run with this device. Recommendations on when to test the control materials are provided in the labeling. 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. Infection Control: The device is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes with EPA registration # 46781-8. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 260 cleaning and disinfection cycles designed to simulate 5 years of single-patient device use (to represent 260 cleanings and 260 disinfections). Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

2. Usability Study: A usability study was performed to assess the readability of the labeling by recruiting untrained lay users who were provided with the test kit containing labeling for the US market. These lay users also completed a questionnaire regarding the clarity of

the instructions and the ease of use of the device. The majority of the users responded that they understood the instructions and were able to successfully operate the device.

3. Readability Assessment: The sponsor performed a readability assessment of the labeling and states that the user manual, strip insert, quick reference guide, and controls insert had a Flesch-Kincaid reading level at the 8th grade level or below.

4. The Customer Care Service Center is available 24/7, 365 days a year. The toll free phone number is 1−855−464−6283.

5. Temperature and Humidity Studies: The sponsor claims an operating condition range of 10 – 40° C and 10 – 90% relative humidity. Combinations of the claimed temperature and humidity operating conditions were evaluated by measuring three levels of patient samples at 10, 25, and 40°C at 10, 50, and 90% humidity using 10 meters. The results demonstrated that the system produces accurate results over the claimed range of operating conditions.

6. Altitude Study: To evaluate the effects of altitude, venous blood samples from donors were spiked to four glucose concentrations (72, 133, 232, and 375 mg/dL) and tested in an altitude chamber set to simulate atmospheric conditions at sea level and10,000 feet. Additionally, one lot of glucose strips was used with 5 meters using blood that covered a glucose range of 43-548 mg/dL. Each venous blood sample was also tested by the YSI 2300 analyzer. The meter readings obtained were compared to the YSI method and the percent bias against the YSI results was within ± 10%. Based on the data, the sponsor claims that the Gmate™ VOICE BGMS can be used at altitudes up to 10,000 feet.

7. Hematocrit Study: The sponsor performed a study to evaluate potential interference from hematocrit using five different hematocrit (Hct) levels (20, 30, 40, 50, and 60%) across the glucose measuring range. At each hematocrit level, 5 blood samples at glucose concentration of 50, 100, 150, 230, and 330 mg/dL were tested against the YSI method. Each sample was tested on ten meters using one lot of test strips and the values were compared to the YSI method and the nominal hematocrit level (40%). All individual test results met the sponsor's acceptance criteria.

8. Sample Volume Study: A sample volume study was performed to verify the test strip minimum sample volume requirement and the test strip fill error requirement established for the Gmate™ VOICE BGMS. Venous blood from donors was collected into EDTA anticoagulant tubes. The glucose level was adjusted to 40, 70, 125, 250, and 450 mg/dL. Blood at each concentration was applied to strips at four target sample volumes of 1.0, 0.7, 0.5, and 0.3 µL. Protocols and acceptance criteria were provided and found to be acceptable. The sponsor concluded that sample volume of ≥0.5 µL produced accurate results and samples <0.5 µL give an error code.

9. Voice Function: The sponsor performed a study to validate the voice function of the Gmate™ VOICE BGMS. Twenty-two lay users fluent in English were blindfolded and were asked to interpret the voice prompts and test results. The users indicated that 95% of

the time they were able to clearly understand the voice prompts and test results and that 95.5 % of the time the users indicated that the voice function was satisfactory.

10. EMC Testing: EMC testing was evaluated and certified by IST Co., Ltd. and a declaration of conformity was issued and attached to the file.

11. Software: The software is used to obtain the blood glucose level from the test strips. It includes user interfaces and controls in the hardware and has USART interface. The Sponsor has provided information required for a moderate level of concern instrument, including a device hazard analysis, description, software design specification document, software requirements specifications, traceability, validation and verification testing plan, architecture design, development, and revision level history. There are no unresolved anomalies and this is release version 1.00.00.

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.