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

A. 510(k) Number:
k081703

B. Purpose for Submission:
Clearance of a new device

C. Measurand:
Whole blood glucose

D. Type of Test:
Whole blood glucose concentration through a quantitative amperometric assay (Glucose Oxidase)

E. Applicant:
Entra Health Systems, Ltd.

F. Proprietary and Established Names:
Myglucohealth 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
   Class I (reserved)

3. Product code:
   NBW, CGA
   JJX

4. Panel:
   75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) for use:
   The Myglucohealth glucose monitoring system provides a quick and easy way for diabetic patients to measure and self-monitor blood glucose levels. The system is

comprised of the MGH-BT1 (w/Bluetooth wireless download capability) or the MGH-1 (w/o Bluetooth) blood glucose meter, control solution and test strips that carry a biosensor used for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, hand, upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals. The results obtained are plasma calibrated to allow for easy comparison to the laboratory method. Further, results from either meter may be uploaded to a memory device through a standard RS32 connection, or, with the –BT1 model, wirelessly transmitted to a Bluetooth capable PC or Cell phone. The Myglucohealth glucose monitoring systems are not to be used for the diagnosis or screening of diabetes or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

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:
   Myglucohealth Glucose Monitoring System

I. Device Description:

The Myglucohealth Glucose Monitoring System is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 3 seconds. The control solutions available are used to test the performance of the device.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   HMD Biomedical LLC, Evolution Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k072369

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection method	Amperometry	Same
Enzyme	Glucose oxidase (Aspergillus niger)	Same
Mediator	Hexaammineruthenium (III) Chloride	Same

Similarities		
Item	Device	Predicate
Electrode	Carbon electrode	Same
Test range	20-600 mg/dL	Same
Test time	3 seconds	Same
Sample volume	0.3 uL	Same
Hematocrit range	20-60%	Same
Memory capability	365 tests with date and time	Same
Power	3V Li battery	Same
Battery life	1 year	Same
Temperature range	50-104^{0}F	Same
Humidity range	R.H. 10-90%	Same
Size (L x W x H)	76 x 56 x 18	Same
Weight	45 grams with battery	Same
Software	Evolution Diabetes Management Software	Same
Data uploading capability	MGH-1 model: To PC via R232 cable	Same

Differences		
Item	Device	Predicate
Data uploading capability	MGH-BT1 model: Wireless uploading to Bluetooth paired PC or cell phone.	To PC via R232 cable

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

- ISO 15197:2003, In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Test Systems for Self Managing Diabetes Mellitus

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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Within-Run

The testing used venous blood in a heparin blood collection tube. Glucose was added to the blood to prepare 5 different levels of glucose concentration 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, 10 strips

were tested on 10 meters (10 strips for each meter) using 1 lot of test strips. Results are summarized below:

Range (mg/dL)	N	Lot: S4FC06F07		
		Mean (mg/dL)	SD (mg/dL)	CV (%)
20~50 mg/dL	100	40.1	2.1	5.3
51~110 mg/dL	100	77.3	2.2	2.8
111~150 mg/dL	100	126.3	4.2	3.3
151~250 mg/dL	100	218.4	7.1	3.3
251~400 mg/dL	100	372.1	7.4	2.0

Day-to-Day Precision
10 Meters, 1 lot of test strips, and 3 glucose solutions were prepared. Each solution was tested once a day for 10 days. Results are summarized below:

Solution Level	N	mean (mg/dL)	SD (mg/dL)	CV (%)
Low	100	41.3	1.6	3.9
Normal	100	113.0	3.3	2.9
High	100	342.5	9.6	2.8

b. Linearity/assay reportable range:
Heparinized venous whole blood was spiked or glycolyzed to 11 concentrations between 27 mg/dL and 552 mg/dL (confirmed by YSI) then tested with the Myglucohealth Glucose Monitoring System and YSI. Each dilution was tested five times using the Myglucohealth system and in duplicate by YSI. Regression analysis showed a linear relationship between the Myglucohealth system and the YSI method: $y = 1.005x – 1.852$, $R = 0.999$.

The sponsor claims 20 mg/dL as the lowest detectable limit. This is supported by the accuracy testing, which had samples at and near 20 mg/dL (see section M.2.a. below).

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The sponsor provided the traceability and value assignment procedure for control solutions used in this device. They are prepared at three target concentrations by gravimetric addition of glucose to an aqueous matrix. The glucose concentration of the control solutions are verified with the YSI reference method and expected values are verified for each new manufactured lot of strips.

Shelf life studies show that the unopened test strips have a 26 month life-span and 3 months shelf-life once a vial of strips is opened. Unopened controls have a 26 month shelf life and are stable for 3 months after first use.

d. Detection limit:

The measuring range of the system is 20 - 600 mg/dL. This range was verified by the linearity and accuracy studies (section M.1.b. above and M.2.a below).

e. Analytical specificity:

Spiked whole blood samples containing low, mid, and high levels of glucose (60, 110, and 380 mg/dL), with and without interfering substances, were prepared to test common endogenous and exogenous substances for interference. The highest levels tested for each interferant (in mg/dL) and the levels of glucose tested are summarized below:

Low glucose level:

Interferences	High interference conc.(mg/dL)	Blank mean (mg/dL)	High interference mean (mg/dL)	Difference (mg/dL)
Acetaminophen	***20***	54.8	55.6	***0.8***
Bilirubin	***40***	53.0	55.4	***2.4***
Gentistic acid	***50***	54.8	62.0	***7.2***
Uric acid	***20***	53.0	55.8	***2.8***
Levo-Dopa	***4***	56.4	52.6	***-3.8***
Creatinine	***30***	54.8	52.2	***-2.6***
Methyl-Dopa	***2.5***	56.4	53.4	***-3.0***
Tolazamide	***5***	53.0	48.6	***-4.4***
Dopamine	***13***	54.8	58.2	***3.4***
Ascorbate	***3***	54.8	62.0	***7.2***
EDTA	***640***	54.8	59.4	***4.6***
Glutathione	***1***	54.8	51.6	***-3.2***
Heparin	***1,000***	54.8	58.8	***4.0***
Ibuprofen	***40***	55.2	61.6	***6.4***
Salicylic acid	***50***	54.8	49.8	***-5.0***
Tetracycline	***0.4***	54.8	56.6	***1.8***
Tolbutamide	***100***	55.2	47.8	***-7.4***
Urea	***500***	54.8	56.0	***1.2***
Cholesterol	***500***	55.6	57.8	***2.2***
TG	***3000***	56.0	60.4	***4.4***
Galactose	***50***	54.8	56.8	***2.0***
Xylose	***10***	54.8	55.2	***0.4***
Maltose	***300***	54.8	56.6	***1.8***

Mid glucose level:

Interferences	High interference conc.(mg/dL)	Blank mean (mg/dL)	High interference mean (mg/dL)	Error%
Acetaminophen	***20***	111.8	113.2	***1.3***
Bilirubin	***40***	115.0	118.8	***3.3***
Gentistic acid	***50***	111.8	120.6	***7.9***
Uric acid	***20***	115.0	117.4	***2.1***
Levo-Dopa	***4***	106.8	103.6	***-3.0***
Creatinine	***30***	111.8	108.4	***-3.0***
Methyl-Dopa	***2.5***	106.8	103.4	***-3.2***
Tolazamide	***5***	115.0	110.8	***-3.7***
Dopamine	***13***	111.8	115.4	***3.2***
Ascorbate	***3***	111.8	119.2	***6.6***
EDTA	***640***	111.8	115.0	***2.9***
Glutathione	***1***	111.8	108.2	***-3.2***
Heparin	***1,000***	111.8	115.8	***3.6***
Ibuprofen	***40***	118.2	126.4	***6.9***
Salicylic acid	***50***	111.8	106.6	***-4.7***
Tetracycline	***0.4***	111.8	112.4	***0.5***
Tolbutamide	***100***	118.2	110.0	***-6.9***
Urea	***500***	111.8	112.6	***0.7***
Cholesterol	***500***	121.8	124.0	***1.8***
TG	***3000***	124.4	127.4	***2.4***
Galactose	***50***	111.8	113.2	***1.3***
Xylose	***10***	111.8	112.0	***0.2***
Maltose	***300***	111.8	113.2	***1.3***

High glucose level:

Interferences	High interference conc.(mg/dL)	Blank mean (mg/dL)	High interference mean(mg/dL)	Error%
Acetaminophen	***20***	380.0	387.0	***1.8***
Bilirubin	***40***	378.6	390.2	***3.1***
Gentistic acid	***50***	380.0	406.0	***6.8***
Uric acid	***20***	378.6	385.0	***1.7***
Levo-Dopa	***4***	375.2	362.4	***-3.4***
Creatinine	***30***	380.0	370.4	***-2.5***
Methyl-Dopa	***2.5***	375.2	363.6	***-3.1***
Tolazamide	***5***	378.6	365.2	***-3.5***
Dopamine	***13***	380.0	395.6	***4.1***

Ascorbate	***3***	380.0	407.2	***7.2***
EDTA	***640***	380.0	391.6	***3.1***
Glutathione	***1***	380.0	365.8	***-3.7***
Heparin	***1,000***	380.0	395.4	***4.1***
Ibuprofen	***40***	373.0	397.2	***6.5***
Salicylic acid	***50***	380.0	366.4	***-3.6***
Tetracycline	***0.4***	380.0	384.2	***1.1***
Tolbutamide	***100***	373.0	352.8	***-5.4***
Urea	***500***	380.0	375.2	***-1.3***
Cholesterol	***500***	55.6	386.4	***2.3***
TG	***3000***	56.0	388.8	***3.7***
Galactose	***50***	380.0	382.8	***0.7***
Xylose	***10***	380.0	380.0	***0.0***
Maltose	***300***	380.0	383.4	***0.9***

An altitude study was performed with 9 blood samples ranging from 31 to 534 mg/dL. Testing was performed at altitudes of sea level and 10,000 feet using a chamber to simulate high altitude conditions. The test results showed that at 9 different levels of glucose at sea level conditions, there is a difference of -2.0 - 3.0 mg/dL and bias of -5.2 - 3.9% with a linear regression of $y = 0.9938x + 1.722$ $R^2 = 0.9993$ versus a reference method. Results showed that at 9 different levels of glucose at the simulated 10,000 feet conditions there is a difference of -2.0 - 4.0 mg/dL and bias of -3.0 - 5.9% with a linear regression of $y = 1.0365x – 3.8386$ $R^2 = 0.9991$ versus a reference method. The results demonstrate no significant interference due to altitude at 10,000 feet.

Hematocrit interference was evaluated by adjusting the glucose concentrations and hematocrit levels of venous blood samples from several donors. The venous blood samples were spiked to 8 glucose concentration levels (30, 70, 120, 180, 250, 370, 480, 550 mg/dL). The hematocrit levels were adjusted to 20, 30, 40, 50, and 60%. 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, with over 90% of data within ± 10 mg/dL, when glucose concentrations were ≤75 mg/dL, and bias did not exceed ±15%, with over 90% of data within ± 10 %, when glucose concentrations were >75 mg/dL, within the claimed hematocrit range of 20% to 60%.

f. Assay cut-off:
Not Applicable.

2. Comparison studies:
   a. Method comparison with predicate device:
   To demonstrate the accuracy performance of the Myglucohealth system, a total of 165 samples were tested at a hospital using the finger as a testing site. Only unaltered capillary blood samples were used for glucose concentrations of 50 mg/dL to

400mg/dL. To obtain additional samples with glucose <50mg/dL, capillary blood samples were collected with an appropriate anticoagulant and incubated to allow hydrolysis to occur. To obtain additional samples with glucose >400mg/dL, capillary blood samples were collected with an appropriate anticoagulant and then supplemented with glucose. The samples ranged from 20 to 526 mg/dL. Patients obtained their own samples and measured their glucose using the Myglucohealth system following reading the instructions. A healthcare professional then obtained a capillary whole blood sample in a capillary heparin tube from the patient to measure the blood glucose level with laboratory method. Results are summarized below:

<75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
29/32 (91%)	32/32 (100%)	32/32 (100%)

≥75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
87/133 (65%)	123/133 (92%)	130/133 (98%)	132/133 (99%)

To demonstrate the accuracy performance of the alternate testing sites (upper arm, forearm, calf, thigh, ventral palm, dorsal hand) for the Myglucohealth system a total of 150 patients performed a finger stick and sampled from each alternate site. A healthcare professional then performed the same testing on each patient. The range of tested values for these samples was 68-537 mg/dL. The patient's alternate site testing (AST) from each site was compared to their fingerstick results. The healthcare professional's alternate site testing (AST) from each site on the patient was compared to the healthcare professional's testing of the patient's fingerstick result. Additionally, the patient's results were compared to the results on the patient obtained by the healthcare professional (HP). The results of all these comparisons showed that ISO 15197 accuracy criteria (95% of the individual glucose results shall fall within ±15 mg/dL of the results of the reference method (fingerstick or HP result) at glucose concentration <75mg/dL and within 20% at glucose concentration ≥75mg/dL) were met for all alternate sites.

Patient	Patient Dorsal Hand vs. Patient Fingerstick	Patient Ventral Palm vs. Patient FingerStick	Patient Forearm vs. Patient FingerStick	Patient Upper Arm vs. Patient FingerStick	Patient Thigh vs. Patient FingerStick	Patient Calf vs. Patient FingerStick
Samples < 75 mg/dL within ±15 mg/dL	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)	5/5 (100%)
Samples	145/145	145/145	145/145	145/145	145/145	145/145

≥ 75 mg/dL within ± 20%	(100%)	(100%)	(100%)	(100%)	(100%)	(100%)
Total	150/150 (100%)	150/150 (100%)	150/150 (100%)	150/150 (100%)	150/150 (100%)	150/150 (100%)

HP	HP Dorsal Hand vs. HP Fingerstick	HP Ventral Palm vs. HP FingerStick	HP Forearm vs. HP FingerStick	HP Upper Arm vs. HP FingerStick	HP Thigh vs. HP FingerStick	HP Calf vs. HP FingerStick
Samples < 75 mg/dL within ±15 mg/dL	6/6 (100%)	6/6 (100%)	6/6 (100%)	6/6 (100%)	6/6 (100%)	6/6 (100%)
Samples ≥ 75 mg/dL within ± 20%	144/144 (100%)	144/144 (100%)	144/144 (100%)	144/144 (100%)	144/144 (100%)	144/144 (100%)
Total	150/150 (100%)	150/150 (100%)	150/150 (100%)	150/150 (100%)	150/150 (100%)	150/150 (100%)

Patient vs. HP	Patient Dorsal Hand vs. HP Dorsal Hand	Patient Ventral Palm vs. HP Ventral Palm	Patient Forearm vs. HP Forearm	Patient Upper Arm vs. HP Upper Arm	Patient Thigh vs. HP Thigh	Patient Calf vs. HP Calf
Samples < 75 mg/dL within ±15 mg/dL	6/6 (100%)	6/6 (100%)	7/7 (100%)	6/6 (100%)	8/8 (100%)	5/5 (100%)
Samples ≥ 75 mg/dL within ± 20%	144/144 (100%)	144/144 (100%)	143/143 (100%)	144/144 (100%)	142/142 (100%)	145/145 (100%)
Total	150/150 (100%)	150/150 (100%)	150/150 (100%)	150/150 (100%)	150/150 (100%)	150/150 (100%)

A user study was performed with the Myglucohealth system by comparing blood glucose results obtained by patients with those obtained using a laboratory method. One hundred lay users were given a questionnaire to gauge the user's ability to

understand the labeling and to evaluate the Myglucohealth system. The participants were provided with a kit (Myglucohealth Test Kit System) as labeled and packaged as it would be for the US market in English (only). Participants performed a fingerstick and measured their blood glucose on the Myglucohealth System. Following this, a healthcare professional performed a fingerstick on the patient and used capillary whole blood to measure the patient's blood glucose. The healthcare professional also collected capillary whole blood in a capillary anticoagulant heparin tube. This capillary whole blood was centrifuged, and then the blood glucose measured using the laboratory method. The results met the sponsor's acceptance criteria of 95% of the individual glucose results falling within ±15 mg/dL of the laboratory method's result at glucose concentrations of <75mg/dL and within 20% of the laboratory method's result at glucose concentrations ≥75mg/dL.

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 in people without diabetes in their strip labeling:

   Fasting 70-110 mg/dL[1]
   Two-hours after meals: less than 140 mg/dL[2]

   [1]Stedmans Medical Dictionary, 27th Edition, 1999, p755.
   [2]American Diabetes Association Clinical Practice Recommendations 2004, Diabetes Care Supplement 1, p. S9.

N. Instrument Name:
Myglucohealth 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, ventral palm, hand, upper arm, forearm, calf, and thigh. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:
   This meter is an auto code meter. A color tag on the back of the test strips provides lot specific calibration information. No calibration by the user is required.

6. Quality Control:
   Glucose control solutions at three different concentrations can be run with this device. When a test strip is inserted into the meter, the control mode can be activated. 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. 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:

None.

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.