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

A. 510(k) Number:

k132180

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood

D. Type of Test:

Quantitative Amperometric assay (FAD-Glucose Oxidase)

E. Applicant:

Ideal Life, Inc.

F. Proprietary and Established Names:

IDEAL LIFE GlucoManager Blood Glucose Monitoring System, Model GMM0002

G. Regulatory Information:

1. Regulation section:
   862.1345, Glucose Test System
   862.2100, Calculator/Data Processing Module, For Clinical Use
   862.1660, Single (Specified) Analyte Controls (Assayed and Unassayed)

2. Classification:
   Class II
   Class I, reserved

3. Product code:
   NBW, Blood Glucose Monitoring System
   CGA, Glucose Test System
   JQP, Calculator/Data Processing Module, For Clinical Use
   JJX, Quality Control material (assayed and unassayed)

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below.

2. Indication(s) for use:
   The IDEAL LIFE GlucoManager™ Blood Glucose Monitoring System, Model GMM0002 is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip or alternative sites (palm, forearm, upper arm, calf, and thigh). The system is intended to be used by a single patient and should not be shared.

   The IDEAL LIFE GlucoManager™ Blood Glucose Monitoring System, Model GMM0002 is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is not to be used for the diagnosis of or screening for diabetes or for neonatal use. Alternative site testing should only be done during steady state times when blood glucose is not changing rapidly.

   The IDEAL LIFE Blood Glucose Test Strips, Model: AGS-1112 are for use with the IDEAL LIFE GlucoManager, Model GMM0002 to quantitatively measure glucose in fresh capillary whole blood drawn from the fingertips, palm, forearm, upper arm, calf, and thigh.

   The IDEAL LIFE Control Solution, Model: GCS 0104 is intended for use with IDEAL LIFE GlucoManager, Model GMM0002 and IDEAL LIFE Blood Glucose Test Strips, Model AGS-1112. The control solution can be used to check that the glucose meter and test strips are working properly and that the measurement is accurate.

   IDEAL Life GlucoManager™ Blood Glucose Monitoring System, Model GMM0002 can wirelessly communicate with a communication gateway or an access point such as the IDEAL Life Pod or to the IDEAL Life Gateway application. The IDEAL LIFE Gateway Application receives data wirelessly from IDEAL LIFE devices to transmit over the internet from the user's mobile device. The Gateway Application is intended to aid people at home and health care professionals to review and evaluate historical blood glucose results, to support effective health care management.
   The IDEAL LIFE Gateway application makes no interpretation, evaluation, medical judgment or recommendations for treatment. This device is not intended as a substitute

for medical care.

3. Special conditions for use statement(s):
   For In Vitro Diagnostic use only
   Single patient use only
   Not intended for use on neonates
   Not intended for use on arterial blood, neonates, serum or plasma
   Not intended for use on individuals undergoing oxygen therapy
   Not for use by those in a hyperglycemic-hyperosmolar state, with or without ketosis
   Not for use on critically ill individuals
   Not to be used for individuals who are dehydrated, hypertensive, hypotensive or in shock
   AST should not be used to calibrate CGMs or in insulin dose calculations
   AST should only be used during periods of steady state blood glucose conditions
   Do not use for screening or diagnosis of diabetes mellitus

4. Special instrument requirements:
   IDEAL Life GlucoManager, Model GMM0002

I. Device Description:

The IDEAL LIFE GlucoManager™ GMM0002 Blood Glucose Monitoring System, Model GMM0002 consists of the IDEAL LIFE GlucoManager, Model GMM0002, IDEAL LIFE test strips, Model AGS-1112 and IDEAL Life Control solutions (three levels). The IDEAL LIFE GlucoManager™ 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 5 seconds. The IDEAL LIFE Control Solutions come in three levels (level I, II, and III). The control solutions are used to test the performance of the device. It uses the same technological characteristics for testing as its predicate device. Level II will be provided in the system kit.

The IDEAL LIFE GlucoManager™ can wirelessly communicate via Bluetooth and Internet with a communication gateway (the optional IDEAL LIFE Pod™) or an access point to transmit blood glucose information to be displayed on a personal computer.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   AG-608N Single Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k110017

3. Comparison with predicate:

Similarities		
Item	Candidate Device IDEAL LIFE GlucoManager GMM0002 k132180	Predicate Device AG-608N Single BGMS k110017
Intended use	Quantitative measurement of blood glucose in fresh capillary whole blood	Same
Detection Method	Amperometry	Same
Enzyme	Glucose Oxidase	Same
Measuring range	20-600mg/dL	Same
Sample Volume	0.7μL	Same
Sample type	Capillary whole blood from fingertip	Same
Alternate site testing (AST)	Palm, forearm, upper arm, calf, thigh	Same
Hematocrit range	20-60%	Same
Operating temperature range	50°F-104°F	Same
Altitude study	10,744 feet	Same
Display	LCD	Same
Test time	5 seconds	Same
Coding	No coding required	Same
Test start	Automatic	Same

Differences		
Item	Candidate Device IDEAL LIFE GlucoManager GMM 0002 k132180	Predicate Device AG-608N Single BGMS k110017
Memory	575 events including time and date display	500 events including time and date display
Power source	DC 3V (2*AAA)	DC 3V (CR2032)
Dimensions	77.3mm x 60.2mm x 25mm	87mm x 53mm x 9.9mm
PC connection/transmission function	Bluetooth	USB
Test strips	AGS-1112 Test strip	AGS-1000N Test strip

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

ISO 15197:2003 (E): In vitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
IEC 61010-1: 2001: Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements

IEC 61010-2-101: 2002: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 61326-1:2006: Electrical equipment for measurement, control and laboratory use – EMC requirements part 1: General requirements
EN 61326-2-6 Electrical equipment for measurement, control and laboratory use –EMC requirements Part 2-6: Particular requirements-In vitro diagnostic (IVD) medical equipment
AAMI / ANSI / ISO 14971:2007/(R) 2010 (Corrected 4 October 2007), Medical devices - Applications of risk management to medical devices.

L. Test Principle:

IDEAL LIFE GlucoManager GMM 0002 Blood Glucose Monitoring System measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the strip. The meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

M. Performance Characteristics (if/when applicable): *All performance characteristics were conducted on the IDEAL LIFE GlucoManager, Model GMM0002 with the IDEAL LIFE test strips model AGS-1112.*

1. Analytical performance:

a. Precision/Reproducibility:

Venous blood spiked with five different glucose concentrations (30-50, 51-110, 111-150, 151-250, and 251-400mg/dL) was tested on three lots of test strips on 10 meters. Ten replicates were tested per meter, test strip lot and glucose concentration for a total of 100 replicates. Results are summarized below:

With-in day Precision:

Glucose level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	31.5	2.4	7.50
51-110	105.6	3.9	3.73
111-150	121.7	4.6	3.74
151-250	182.8	7.0	3.85
251-400	263	10.2	3.86

In addition to the study above, the sponsor also evaluated day-to-day precision using three control solutions with three concentrations of glucose (30-50, 96-144, 280-420mg/dL). Reproducibility was evaluated over a ten day period with three lots of test strips and 10 meters. Results are summarized below:

Reproducibility:

Control Solution	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1 30-50mg/dL	54.5	4.1	7.5
Level 2 96-144mg/dL	97	3.7	3.80
Level 3 280-420mg/dL	345.2	13.3	3.86

b. Linearity/assay reportable range:

The claimed measuring range for this device is 20-600 mg/dL. The sponsor performed linearity studies using venous whole blood samples with 11 different glucose concentration levels covering the full measuring range (20.5, 39.2, 99.4, 160.1, 224.5, 273.7, 348.6, 420.8, 505.3, 570.6, 599.6mg/dL). Measurements were taken 5 times for each level and the values were compared to YSI. Linear regression analysis is summarized below:

$Y=0.9948x+2.6936$; $R^2=0.9984$

The results support the claimed measuring range of 20-600mg/dL.

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

Traceability:

The IDEAL LIFE GlucoManager GMM0002 Blood Glucose Monitoring System is traceable to NIST reference standard reference material (SRM) 965b.

Stability:

Test strip stability was assessed with accelerated studies, in-use and on-going real time studies. For unopened vial stability, accelerated testing of the test strips was performed and real-time testing is ongoing to confirm the accelerated results. Testing support the claimed unopened vial storage of 18 months when stored at 39°F to 86°F (4°C to 30°C) with relative humidity 10-85% and a 90 day stability after opening when stored at 39°C to 86°F (4°C to 30°C) with relative humidity 10-85%.

The stability of the control solution was established in k110017. The claimed stability is 24 months when stored at 39°F-86° and 90 day stability after opening when stored at 39°F-86°F.

Value assignment:

The IDEAL LIFE Control Solution, Model: GCS 0104 (Level I, Level II, Level III) value assignment was established using ten GMM0002 glucose meters and a single lot of AGS-1112 blood glucose test strips. Each level of control solution was tested 100 times by the GMM0002 system. The control range for each control solution is listed on the test strip vial. The control ranges on the label are within ±20% of the

mean value for each level. The user is directed to compare their control result with the range printed on the test strip vial.

d. Detection limit:

The measuring range of the device is 20-600mg/dL. This range was validated via linearity study. See section M.1.b.

e. Analytical specificity:

The sponsor performed interference studies with spiked venous whole blood samples at two glucose concentrations (80mg/dL and 300mg/dL) that were prepared and divided into a test sample and control sample. The potential interferents (2 levels-therapeutic and high) were added to the sample and each sample was tested 5 times. The following table lists the concentrations of each substance at which no significant interference was detected.

Potential Interferent	Concentration at which no significant interference is observed (mg/dL)
Acetaminophen	5.0
Ascorbic acid	2.0
Ibuprofen	50
L-Dopa	0.45
Methyl dopa	0.75
Dopamine	0.03
Salicylate	60
Tolbutamide	24
Bilirubin	15
Triglyceride	2000
Uric acid	10
Creatinine	17
Hemoglobin	250

The sponsor also performed interference studies with spiked venous whole blood samples spiked at three glucose concentrations (85mg/dL, 120mg/dL and 350mg/dL). The potential interferents were added to the sample and each sample was tested 5 times. The following table lists the concentrations of each substance at which no significant interference was detected.

Potential Interferent	Concentration at which no significant interference is observed (mg/dL)
Maltose	350
Xylose	100
Galactose	15.1

The sponsor has the following limitations in their labeling: The following substances at levels greater than normal or therapeutic levels may cause significant interference resulting in an

inaccurate result: ascorbic acid, uric acid, acetaminophen, dopamine, methyl dopa, L-dopa, Tolbutamide, Bilirubin and Hemoglobin.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy:

System accuracy was evaluated according to ISO 15197. The sponsor performed system accuracy evaluation comparing GMM0002 to YSI 2300. Testing was performed by two professionals on a total of 100 fresh capillary whole blood samples from the finger, palm, forearm, upper arm, calf and thigh, using 2 meters and 3 test strip lots over 10 days with glucose concentrations ranging from 45-539mg/dL. After finger blood sample test finished, alternative site testing (AST) samples were obtained by the HCP. The AST sites included samples taken from the palm, forearm, upper arm, calf and thigh. The results for a singlet set of data relative to the reference method are summarized in the tables below:

Professional vs. YSI

Sample site	Concentration (mg/dL)	Slope	y-intercept	R
Finger	46.8-537	1.001	1.68	0.9826
Palm	48.2-539.8	1.001	1.96	0.9823
Forearm	46.5-538.3	1.015	0.65	0.9830
Upper Arm	45.3-539.4	1.011	0.88	0.9901
Calf	49.3-539.7	1.005	1.86	0.9842
Thigh	48.1-536.3	1.017	-0.03	0.9865

For glucose concentrations <75mg/dL

Sample site	Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
Finger	4/6 (66%)	6/6 (100%)	6/6 (100%)
Palm	5/7 (71%)	7/7 (100%)	7/7 (100%)
Forearm	4/7 (57%)	7/7 (100%)	7/7 (100%)
Upper arm	5/7 (71%)	7/7 (100%)	7/7 (100%)
Calf	4/7 (57%)	7/7(100%)	7/7 (100%)
Thigh	6/7 (86%)	7/7 (100%)	7/7 (100%)

For glucose concentrations ≥75mg/dL

Sample site	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Finger	65/94 (69%)	92/94 (98%)	94/94 (100%)	94/94 (100%)
Palm	62/93 (67%)	89/93 (96%)	93/93 (100%)	93/93 (100%)
Forearm	70/93 (75%)	92/93 (99%)	93/93 (100%)	93/93 (100%)
Upper Arm	63/93 (68%)	92/93 (99%)	93/93 (100%)	93/93 (100%)
Calf	62/93 (67%)	90/93 (97%)	93/93 (100%)	93/93 (100%)
Thigh	71/93 (76%)	92/93 (99%)	93/93 (100%)	93/93 (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 Performance Study:
The lay user study was conducted following ISO 15197. To assess the performance of the GMM0002 in the hands of the intended users, the sponsor performed a study with 100 lay users. The study was performed at four sites. The subjects were provided the product instructions for use but not given any additional instructions. Each subject performed finger stick and alternative sites (palm, forearm, upper arm, calf, and thigh) testing on their own. After the users self-test, the HCP measured the user's fingerstick and AST capillary blood on the GMM0002 system and a second sample was measured on the YSI 2300. The range of glucose values for the samples measured by the reference method was 55-339mg/dL. Results are summarized below:

Lay user vs. YSI 2300

Sample site	Slope	Y-intercept	R
Finger	1.018	-3.60	0.9879
Palm	1.023	-4.90	0.9875
Forearm	1.024	-4.91	0.9858
Upper Arm	1.029	-5.09	0.9838
Calf	1.018	-3.09	0.9846
Thigh	1.026	-3.42	0.9852

For glucose concentrations <75mg/dL

Sample site	Within ±5mg/dL	Within ±10mg/dL	Within ±15mg/dL
Finger	6/8 (75%)	8/8 (100%)	8/8 (100%)
Palm	1/9 (11.1%)	7/9 (77.8%)	9/9 (100%)
Forearm	4/12 (33.3%)	8/12 (66.7%)	12/12 (100%)
Upper Arm	4/11 (36.4%)	8/11 (72/7%)	11/11 (100%)
Calf	4/8 (50%)	5/8 (62.5%)	8/8 (100%)
Thigh	4/10 (40%)	6/10 (60%)	10/10 (100%)

For glucose concentrations ≥75mg/dL

Sample site	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Finger	44/92 (47.8%)	69/92 (75%)	92/92 (100%)	92/92 (100%)
Palm	45/91 (49.5%)	72/91 (79.1%)	85/91 (93.4%)	91/91 (100%)
Forearm	42/88 (47.7%)	65/88 (73.9%)	82/88 (93.2%)	88/88 (100%)
Upper arm	33/89 (37.1%)	64/89 (71.9%)	82/89 (92.1%)	87/89 (97.7%)
Calf	40/92 (43.5%)	68/92 (73.9%)	82/92 (89.1%)	89/92 (96.7%)
Thigh	39/90 (43.3%)	67/90 (74.4%)	83/90 (92.2%)	88/90 (97.8%)

4. Clinical cut-off**:**
   Not applicable

5. Expected values/Reference range:
   Expected blood glucose levels for people without diabetes:

Time of Day	People without Diabetes
Before meal (fasting)	<100mg/dL
Two hours after meals	<140mg/dL

Source: American Diabetes Association. Standards of Medical Care in Diabetes-2014. Diabetes Care 2014, 37 (suppl. 1) S14-S80.

N. Instrument Name:

IDEAL LIFE GlucoManager, Model GMM0002

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 X or No ___

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?
Yes X or No ___

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 device is intended to be used with capillary whole blood from the finger, palm, forearm, upper arm, calf and thigh. The whole blood sample is applied directly to the test strip by capillary action therefore there are no special handling or storage issues.

5. Calibration:
This is non-coding device therefore no calibration is required by the user.

6. Quality Control:
IDEAL LIFE GlucoManager uses the IDEAL LIFE Control Solutions. The control solutions come in three levels. The sponsor states that level II will be provided in the system kit.

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

1. Altitude Study

An altitude study was performed in three altitude simulation chambers set at sea level, 3,280ft (1000m), 6,561ft (2000m), and 10,744ft (3275m) with 20 venous whole blood samples with glucose concentrations ranging from 56.5 to 438mg/dL. Each sample was tested with four meters and one test strip lot and the results were compared to YSI. The results demonstrate acceptable bias to the reference to support the claims in the labeling that altitudes up to 10,744 feet have no significant effect on blood glucose measurements from the IDEAL LIFE GlucoManager GMM0002 Monitoring System.

2. Hematocrit Study

The effect of different hematocrit levels were evaluated using venous whole blood samples with hematocrit levels of 20-60% (20, 25, 30, 35, 40, 45, 50, 55, 60%) spiked with five glucose concentrations (22.6, 76.5, 152, 256, 354, 453, 596mg/dL) distributed across the measuring range. The samples were tested with three meters and one lot of

test strips. The results were compared to YSI and the normal 40% hematocrit. The percent bias of the IDEAL LIFE GlucoManager GMM0002 meter results relative to YSI demonstrated adequate performance to support the claimed hematocrit range of 20-60%.

3. Sample volume

A minimum sample volume study was performed using seven venous whole blood samples with glucose concentrations ranging from 46.5mg/dL to 455mg/dL to evaluate effect of different sample volumes (0.5uL, 0.6uL, 0.7uL, 1.0uL, 2.0uL) on the performance of the device. Results at each sample volume were compared to the corresponding YSI values. Results from these studies support the claimed minimum sample volume of 0.7uL.

4. Infection Control Studies

The IDEAL Life GlucoManager GMM0002 is intended for single patient use. Disinfection efficacy was established in k110017. Robustness studies were performed by the sponsor demonstrating that there was no change in performance or external materials of the meter and landing device after 11,000 pre-cleanings and 11,000 disinfection steps with the Cavi WipesTM (EPA Registration # 46781-8). The robustness studies were designed to simulate 5 years of single patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

5. Temperature and Humidity Studies

Temperature and humidity operating conditions were evaluated using three GMM0002 meters and one lot of test strips with fresh venous whole blood samples at three glucose levels (low, normal, high) for temperatures ranging from 50 °F to 104°F (10°C to 40°C) and relative humidity from 25% to 80% including extreme conditions of temperature and humidity, e.g. lowest humidity with lowest and highest temperature and highest humidity with lowest and highest temperature. Protocol and acceptance criteria were provided and found to be acceptable. The results supported the sponsor's claimed operating temperature from 50°F to 104°F and relative humidity range from 25%- 80%.

6. **EMC testing**

The sponsor provided documentation certifying that acceptable electromagnetic testing (EMC) had been performed.

7. Readability Assessment

A SMOG reading level assessment was conducted of the GlucoManager GMM0002 instructions for use and the quick installation guide was assessed, giving a readability grade level of 7.5 and 7.8 respectively. Test strip and Control solution instruction for use were assessed with a readability level of 7.7 and 7.2 respectively.

8. **Data Transmission**

IDEAL LIFE GlucoManager GMM0002 Blood Glucose monitoring system has a Bluetooth function. The sponsor performed the following test scripts:

Test scripts for Gateway Application and GlucoManager GMM0002
This test script is to ensure that the IDEAL LIFE GlucoManager GMM0002 will be able to correctly send readings via the IDEAL Life Gateway Application to IDEAL LIFE Cloud. The acceptance criteria are that readings shall be saved on the Ideal Life DB with the correct values. Five tests were performed with the IDEAL LIFE GlucoManager GMM0002 via IDEAL LIFE Gateway Application. All executed test cases have the status of PASS.

No Data Lost between Gateway Application and Manager Device
This test script is to ensure that IDEAL LIFE Managers, including the GlucoManager, will be able to store reading data in their memory and there will be no data loss if Gateway Application fails to transmit readings to IDEAL LIFE Cloud. One test case for each Manager type was performed. All executed test cases have the status of PASS.

9. **Software:** The sponsor provided the results of the device software testing including a traceability analysis, validation and verification testing which were reviewed and found to be adequate.

10. **Human Factors testing:**
A usability test was conducted with twenty-two (22) users of varied computer skill between 18-80 years old. Each user was provided with an IDEAL LIFE GlucoManager GMM0002 and given instructions to upload the Gateway application according to the instructions for use, to measure glucose levels with control solutions and to upload data to the website. Users were asked to complete a survey about the ease of use of the device and software. The positive response to this user test indicates that there are no areas of concern about the usability of the device by the intended users.

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.