

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

A. 510(k) Number:

k131173

B. Purpose for Submission:

Modified device: Removal of calculating average function, addition of data transmission functionality, and changed the brand name of the glucose meter, test strips, and glucose solutions.

C. Measurand:

Capillary whole blood glucose from the finger

D. Type of Test:

Quantitative, amperometric assay, glucose dehydrogenase (GDH-FAD)

E. Applicant:

HMD Biomedical, Inc.

F. Proprietary and Established Names:

FIA Blood Glucose Monitoring System (G2)

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1345

21 CFR § 862.1600

2. Classification:

Class II

Class I (reserved)

3. Product code:

NBW - Glucose test system, Over-the-Counter

LFR – Glucose Dehydrogenase

JJX – Single (Specified) Analyte Controls (Assayed And Unassayed)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The FIA Blood Glucose Monitoring System (G2) is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The FIA Blood Glucose Monitoring System (G2) is intended to be used by a single patient and should not be shared.

The FIA Blood Glucose Monitoring System (G2) 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 FIA Blood Glucose Monitoring System (G2) should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The FIA Blood Glucose Test Strips (G2) are for use with the FIA Blood Glucose Monitoring System Meter (G2) to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The FIA Glucose Control Solutions are for use with the FIA Blood Glucose Monitoring Meter (G2) and FIA Blood Glucose Test Strips (G2) to check that the meter and test strips are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):

Over-the-counter use

Single-patient use only

For testing on fingertip only

Not intended for use on neonates

Not for the diagnosis of or screening for diabetes mellitus

Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill, or in a hyperosmolar state

Should not be used on critically ill patients

4. Special instrument requirements:

FIA Blood Glucose Meter (G2)

I. Device Description:

The FIA Blood Glucose Monitoring System (G2) comprises an electrochemical biosensor glucose reagent test strip, a handheld meter, control solutions (Levels I and II; previously cleared under k032985, but renamed as FIA Glucose Control Solutions in this submission), and a check strip. The meter will automatically turn on when a test strip is inserted. A small drop of blood contacts front end aperture which will cause the chamber to fill up on the front end of a test strip. When a beep sound is heard, the chamber is full and test reaction starts. When the test is done, the glucose result will appear on the meter's LCD screen. Data will automatically be stored in memory.

J. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

PRECICHEK Cloudia Blood Glucose Monitoring System – k120064

3. Comparison with predicate:

Similarities		
Item	Subject device FIA Blood Glucose Monitoring System (G2)	Predicate device PRECICHEK Cloudia BGMS (K120064)
Intended use	It is designed to quantitatively measure the concentration of glucose in fresh capillary whole blood	Same
Detection method	Amperometry	Same
Test range	20-600 mg/dL	Same
Operating conditions	50-104 ⁰ F (10-40 ⁰ C), 20-80% RH	Same

Autocoding	Yes	Same
Enzyme	Glucose Dehydrogenase (FAD) (<i>Aspergillus oryzae</i>)	Same
Capillary testing site	Fingertips only	Same
Sample volume	0.5 µl	Same
Memory	999	Same
Test time	5 sec	Same
Time & date setting	Same	Manual

Differences		
Item	Subject device FIA BGMS (G2)	Predicate device PRECICHEK Clouidia BGMS (k120064)
Data transmission	GSM	GSM module equipped, but non-operational
Average	no averaging capabilities	7, 14, 21, 28 days

Controls

Similarities		
Item	Subject device FIA Glucose Control Solutions	Predicate device PRECICHEK Glucose Control Solutions (k032985)
Levels	Same	2
Analyze	Same	D-Glucose

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

1. ISO 15197: In Vitro Diagnostic test systems - Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus
2. IEC 60601-1, Medical electrical equipment- Part 1: General requirements for basic safety and essential performance
3. IEC 60601-1-2, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance
4. CLSI Guideline EP09-A2: Method Comparison and Bias Estimation Using Patient Samples
5. CLSI Guideline EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods
6. CLSI Guideline EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures
7. CLSI Guideline EP07-A2: Interference Testing in Clinical Chemistry
8. FDA Guidance Document: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

L. Test Principle:

The device is comprised of two main parts: a bio-active electrode (test strip) which contains the reagent enzyme glucose dehydrogenase (GDH), and the meter. The blood sample is drawn from fingertip onto the test strip through capillary action. Glucose in the sample reacts with glucose dehydrogenase and potassium ferricyanide in the test strip producing potassium ferrocyanide which is the product proportional to the glucose concentration in the blood sample. During potassium ferrocyanide's oxidation, an electrical current is produced then converted by the meter. The result (glucose level) will be displayed on the monitor.

M. Performance Characteristics (if/when applicable):

The changes; addition of data transmission capability and changing the name of the system, meter, test strips, and controls, does not change the performance of the system; therefore, the testing performed in k120064 is adequate to support the performance claims.

1. Analytical performance:

a. Precision/Reproducibility:

As established in k120064

b. Linearity/assay reportable range:

As established in k120064

The claimed measurement range for this device is 20-600 mg/dL.

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

Traceability

The FIA Blood Glucose Monitoring System (G2) is traceable to the YSI 2300 glucose analyzer through the YSI 2747 calibrator solution (NIST SRM 917b - d-Glucose Standard Reference Material) as established in k120064

Controls:

Value assignment

As established in k032985

Stability

The data support a claimed storage period of 24 months at 50-86 °F for a closed vial, and 90 days at 50-86 °F for an open vial as established in k032985

Test Strip Stability:

The data support a claimed storage period of 18 months at 50-104°F (20-80% RH) for a closed vial, and 90 days at 50-104°F 20-80% RH) for an open vial as established in k120064

d. Detection limit:

The reportable range is 20 to 600 mg/dL based on linearity/reportable range studies above. The low and high detection limits for this device have been set at 20 and 600 mg/dL. Readings below 20 mg/dL and above 600 mg/dL will indicate a "Lo" and "Hi" on the meter display, respectively.

e. Analytical specificity:

As established in k120064

f. Assay cut-off:

Not applicable

2. **Comparison studies:**

a. Method comparison with predicate device:

As established in k120064

b. Matrix comparison:

Not applicable; this device is indicated for fingerstick only

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):*

Lay User Study

As established in k120064

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The sponsor has referenced the following from the American Diabetes Association Standards of Medical Care in Diabetes - 2014, Diabetes Care Vol. 37 (Suppl. 1), p. S16:

Time of Day	Expected Range, Non-diabetes
Before meals	Less than 100 mg/dL
After Meals	Less than 140 mg/dL

N. Instrument Name:

The FIA Blood Glucose Meter (G2)

O. System Descriptions:

1. Modes of Operation:

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 or No

3. Specimen Identification:

Samples are applied directly to the test strip as they are collected. Samples are time and date stamped upon measurement by the glucose meter.

4. Specimen Sampling and Handling:

The meter is intended to be used with capillary whole blood from the finger only. Since the sample is applied immediately and directly to the test strip there are no sample handling or storage issues.

5. Calibration:

The meter is a non-coding meter. No coding is required by the user.

6. Quality Control:

The sponsor recommends two levels of control glucose solution. Level I and Level II. Both are included in the meter kit. An acceptable range is printed on each the glucose test strip vial label. The meter uses an algorithm to automatically recognize the control solution matrix and to prevent the result from being stored as a patient result. Recommendations on when to test the control materials are provided in the labeling. If the control values fall outside the range, the user is referred to the user manual and customer support for troubleshooting and more information.

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

A. Hematocrit

As established in k120064

B. Altitude

As established in k120064

C. Temperature and Humidity

As established in k120064

D. Sample Volume

As established in k120064

E. Infection Control

As established in k120064

F. The purpose of the study is to establish whether lay users can use the meter to accurately

transfer glucose data to the iGlucose System's web-based database. A usability test was conducted with twenty (20) lay users. Each user was provided with a FIA Blood Glucose meter (G2) and the instructions for use. The participants were given instructions to use a control solution to obtain a measurement; the glucose value would then automatically be uploaded to www.iglucose.net. Users were asked to complete a survey about the ease of use of the device and software. 95% of the lay users indicated a 75% satisfaction level with each question, indicating that there are no areas of concern about the usability of the device by the intended users.

- G. Bench testing was performed to demonstrate that the meter could accurately transmit data to a database. The study used a simulated test strip to generate 999 values (full memory) and automatically transmit data after each measurement on three FIA Blood Glucose meters (G2) over the cellular network to a web-based server at www.iglucose.net. All data fields, such as meter serial number, glucose result, time, date, and event mark were 100% accurate.
- H. Software documentation was reviewed and demonstrated that the device was developed under appropriate software lifecycle processes.
- I. FIA Blood Glucose Monitoring System (G2) Owner's Manual cleared under k120064 was modified only to include information and instructions for data transfer to a data management system and name change from PRECICHEK Cloudia Blood Glucose Monitoring System. A readability assessment was provided to demonstrate that the User Manual, test strip package insert and control solution package insert were each written at the 8th grade level.
- J. Electromagnetic Compatibility (EMC) testing was performed. The sponsor provided a certificate of conformity to IEC 60601-1-2, Medical Electrical Equipment- Part 1-2 and ISO 61326-1-6: Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment

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.