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

A. 510(k) Number:

k120064

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

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

E. Applicant:

HMD Biomedical, Inc.

F. Proprietary and Established Names:

 PRECICHEK Cloudia Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LFR – glucose dehydronase, glucose	Class II	21 CFR §862.1345	75
NBW – system, test, blood glucose, over the counter	Class II	21 CFR §862.1345	75
JJX, quality control material (assayed and unassayed)	Class I (reserved)	1 CFR §862.1660	75

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

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

   The PRECICHEK Cloudia Blood Glucose Monitoring System 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 PRECICHEK Cloudia Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

   Precichek ACH Blood Glucose Test Strip
   The PRECICHEK ACH Blood Glucose Test Strips are for use with the PRECICHEK Cloudia Blood Glucose Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

   Precichek Glucose Control Solutions
   The PRECICHEK Glucose Control Solutions are for use with the PRECICHEK Cloudia Blood Glucose Monitoring System and PRECICHEK ACH Blood Glucose Test Strips 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

   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:

   PRECICHEK Cloudia Blood Glucose Meter

I. Device Description:

The PRECICHEK Cloudia Blood Glucose Monitoring System comprises an electrochemical biosensor glucose reagent test strip, a handheld meter, control solutions (Levels I and II; previously cleared under k032985), 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):
   Telcare Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
   k110571

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate
Indications for Use	The PRECICHEK Cloudia Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. The PRECICHEK Cloudia Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.	Same (includes AST)
	The PRECICHEK Cloudia Blood Glucose Monitoring System 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 PRECICHEK Cloudia Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.	Same
	The PRECICHEK ACH Blood Glucose Test Strips are for use with the PRECICHEK Cloudia Blood Glucose Monitoring System to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.	
	The PRECICHEK Glucose Control Solutions are	

Similarities		
Item	Candidate Device	Predicate
	for use with the PRECICHEK Cloudia Blood Glucose Monitoring System and PRECICHEK ACH Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.	
Test Principle	Electrochemical biosensor with carbon electrodes that measures current produced by a chemical reaction.	Same
Sample Type	Fresh capillary whole blood	Same
Measurement Range	20-600 mg/dL	Same
Autocoding	Yes	Same
Speaking Function	No	Same

Differences		
Item	Device	Telcare BGMS, k110571
Enzyme	Glucose Dehydrogenase (GDH-FAD)	Glucose Oxidase
Sample Site	Fingertip	Fingertip, palm, and forearm
Sample Volume	0.5 μL	0.8 μL
Memory Feature	Can store up to 999 patient blood results	Can store up to 300 blood and control data
Measuring Time	5 seconds	6 seconds
Day Average	7,14,21,28 day average glucose result	7, 14, 30 day average glucose result
Meter Dimensions	109 (L) x 60(W) x 16.5(H) mm	100(L)x60(W)x15(H) mm
Weight	100 g	115 g
Test Strip	PreciChek Test Strip	Telcare Test Strip

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

- ISO15197:2003 – In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

- ISO14971:2007 – Medical Devices: Application of risk management to medical devices

- IEC 60601-1 – Medical Electrical Equipment – Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

- EN 60601-1-2: 2007 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

- EN 61326-1:2006 – Electrical equipment for measurement, control, and laboratory use. EMC requirements. General requirements.

- EN 61326-2-6:2006 – Electrical equipment for measurement, control, and laboratory use. Particular requirements. In vitro diagnostic (IVD) medical equipment.

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 ferricyande 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):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   With-in run precision studies were performed using venous blood spiked or aged (per ISO 15197) to desired levels of glucose concentrations indicated in the table below. Samples were tested in replicates of 10 using 10 meters and 3 lots of test strips in a period of one day. The results are summarized below.

   Within-Run Precision

Lot 1	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL	401-600 mg/dL
N	100	100	100	100	100	100
Mean, mg/dL	41.5	99.5	124.0	216.4	340.7	531.7
SD	1.9	4.2	3.9	8.2	11.8	17.6
CV, %	4.5	4.2	3.1	3.8	3.5	3.3

Lot 2	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL	401-600 mg/dL
N	100	100	100	100	100	100
Mean,	40.6	96.4	122.5	208.7	330.1	521.7

mg/dL						
SD	1.7	4.0	3.4	9.0	14.6	16.9
CV, %	4.2	4.2	2.7	4.3	4.4	3.2

Lot 3	30-50 mg/dL	51-110 mg/dL	111-150 mg/dL	151-250 mg/dL	251-400 mg/dL	401-600 mg/dL
N	100	100	100	100	100	100
Mean, mg/dL	42.3	98.4	116.6	204.3	349.3	504.9
SD	1.7	4.2	4.6	9.8	15.8	18
CV, %	4.1	4.3	3.9	4.8	4.5	3.6

Between-run precision studies were performed using 3 levels of glucose control solution in replicates of 10 for 10 consecutive days with 5 meters. Three lots of test strips were used. The results are summarized below.

Between-run Precision

Lot 1	Level I			Level II			Level III		
	Mean, mg/dL	SD	CV, %	Mean, mg/dL	SD	CV, %	Mean, mg/dL	SD	CV, %
	61.5	2.9	4.7	123.9	5.2	4.2	346.8	13.6	3.9

Lot 2	Level I			Level II			Level III		
	Mean, mg/dL	SD	CV, %	Mean, mg/dL	SD	CV, %	Mean, mg/dL	SD	CV, %
	59.6	2.9	4.9	124.3	5.0	4.0	357.4	15.5	4.3

Lot 3	Level I			Level II			Level III		
	Mean, mg/dL	SD	CV, %	Mean, mg/dL	SD	CV, %	Mean, mg/dL	SD	CV, %
	59.0	2.9	4.0	124.2	4.4	3.5	358.2	15.1	4.2

b. *Linearity/assay reportable range:*

Linearity studies were performed on 10 meters using venous blood at 7 levels of glucose concentrations: 22.7, 87.6, 136, 221, 368, 585, and 640 mg/dL. Three lots of test strips were used, with each lot tested 10 times for a total of 70 tests per lot. A linear regression analysis was performed for each lot of strips. The results are summarized below.

	Lot 1	Lot 2	Lot 3
N	70	70	70
Slope	0.9874	0.9789	0.9957
y-intercept	0.7084	2.6401	-0.3980
Correlation coefficient	0.9951	0.9960	0.9925

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

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

The PRECICHEK Cloudia Blood Glucose Monitoring System is traceable to the YSI 2300 glucose analyzer through the YSI 2747 calibrator solution (NIST SRM 917b – d-Glucose Standard Reference Material).

The controls used with this device have been previously cleared (refer to k032985). The sponsor has relabeled the controls for the PRECICHEK Cloudia Blood Glucose Monitoring System to be named as the PRECICHEK Glucose Control Solution.

Test strip stability

Real-time open- and closed-vial studies were performed on one lot of test strips at 3 different temperature and humidity environments: $39^oF\pm3.6^oF$ $(4^oC\pm2^oC)/(45\%\pm5\%RH)$, $86^oF\pm3.6^oF$ $(30^oC\pm2^oC)/(65\%\pm5\%RH)$ and $108^oF\pm3.6^oF$ $(42^oC\pm2^oC)/(75\%\pm5\%RH)$. The data support a claimed storage period of 24 months at $50\text{-}104^oF$ for a closed vial, and 90 days at $50\text{-}104^oF$ for an open vial. The sponsor's protocol and acceptance criteria were reviewed and considered acceptable.

The stability information is provided in the labeling of the test strips and control materials.

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:*

Interference

An interference study was performed (in accordance with CLSI EP7-A2 guidelines) to evaluate the effects of endogenous and exogenous substances on the glucose test results generated by the PRECICHEK Cloudia Blood Glucose Monitoring System. Venous blood samples were obtained from fasting healthy volunteers. Samples were

adjusted to within two glucose concentration ranges: 60-70 mg/dL and 250-350 mg/dL with glucose stock solution. Each glucose concentration was divided into 5 pools, and then the interfering compounds were added to these pools. The control pool (without an interfering compound) was measured by YSI. The remaining four pools were measured with five meters for each glucose concentration. The results are summarized below to show the highest concentration without significant interference (±10% bias).

Substance	Therapeutic/ Physiological Levels (mg/dL)	Highest concentration without interference (mg/dL)
Acetaminophen[1]	1.00-3.00	20
Ascorbic acid[1]	0.40-2.00	2.25
Bilirubin[1]	0.29-1.23	40
Cholesterol[1]	150-250	500
Creatinine[1]	0.60-1.30	10
Dopamine[1]	0.03	20
Ephedrine[2]	0.005-0.01	10
Galactose[1]	0.00-5.00	100
Gentisic Acid[1]	0.20-0.60	2
Glutathione[1]	24.25-32.24	60
Ibuprofen[1]	1.00-7.00	50
Icodextrin[2]	500	600
Lactose[3]	0.00-0.50	20
L-dopa[2]	0.02-0.28	0.8
Maltose[2]	120	200
Methyldopa[1]	0.10-0.75	1.6
Salicyate[1]	9.94-29.95	50
Tetracycline[1]	0.20-0.50	1.6
Tolazamide[2]	3.00	6.25
Tolbutamide[1]	5.40-10.80	64
Triglycerides[1]	150-500	1000
Urea[1]	6.60-85.80	600
Uric acid[1]	2.52-8.00	15
Xylose[2]	57	50
hemoglobin[1]	100-200	450
ethanol[1]	100-200	400
fructose[1]	1.01-5.99	40
Mannitol[4]	1000	1200

Sorbitol[3]	0.044	10

The sponsor has indicated, in the labeling, the following interfering substances will result in inaccurate test results: ascorbic acid (2.25 mg/dL), triglycerides (>1000 mg/dL), uric acid (>15 mg/dL), and xylose (>50 mg/dL).

f.   Assay cut-off:

Not applicable

2. Comparison studies:

a.   Method comparison with predicate device:

System Accuracy

An accuracy study was conducted to compare performance against a reference method (YSI 2300 analyzer). Fresh capillary whole blood samples from 100 volunteers, with glucose concentration ranges indicated below, were tested on the PRECICHEK Cloudia Blood Glucose Monitoring System. Venous blood was collected and measured on the YSI analyzer. For tested samples less than 50 or greater than 400 mg/dL, the samples were pooled and glycolyzed or spiked to a desired level. Three lots of test strips were used on 3 meters. The results are summarized below.

Lot 1

Glucose concentration < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL		Within ± 15 mg/dL
6/13(46%)	11/13(85%)		13/13(100%)
Glucose concentration ≧ 75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
35/87(40%)	67/87(77%)	78/87(90%)	85/87(98%)
Accuracy of Cloudia compared to YSI using capillary whole blood	N=100 $Y=0.987x+1.7432$ $R^2=0.9629$ Sy.x=21.73 Range: 36-463 mg/dL		

Lot 2

Glucose concentration < 75 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/14(43%)	13/14(93%)	14/14(100%)

Glucose concentration ≥ 75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
38/86(44%)	65/86(76%)	78/86(91%)	84/86(98%)
Accuracy of Cloudia compared to YSI using capillary whole blood	N=100 $Y=1.0055x + 2.6293$ $R^2=0.9668$ Sy.x=18.55 Range: 36-460 mg/dL		

Lot 3

Glucose concentration < 75 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
5/13(38%)	12/13(92%)	13/13(100%)

Glucose concentration ≥ 75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
31/87(36%)	74/87(85%)	83/87(95%)	85/87(98%)
Accuracy of Cloudia compared to YSI using capillary whole blood	N=100 $Y=0.977x + 5.8098$ $R^2=0.9655$ Sy.x=19.27 Range: 33-462 mg/dL		

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):

Consumer Study

The sponsor performed a consumer study with trained operators and 150 lay-users. Each lay-user performed their own fingerstick and tested their blood on the PRECICHEK Cloudia meter according to the user's manual. A trained technician performed a second fingerstick on each lay-user for measurement on the YSI. Ten meters were used for the study. The results are summarized below.

Glucose concentration < 75 mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
3/5(60%)	5/5(100%)	5/5(100%)

Glucose concentration ≧ 75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
63/145(43%)	106/145(73%)	130/145(90%)	141/145(97%)

Accuracy of <u>lay users</u> compared to <u>YSI</u> using capillary whole blood on 150 specimens at clinical centers	N=150 Y=1.0193X+4.4269 R^2=0.9612 Sy.x= 11.14 Range: 55~404 mg/dL

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 – 2012, Diabetes Care Vol. 35 (Suppl. 1), p.513:

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

N. Instrument Name:

Precichek Cloudia Blood Glucose Meter

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 __X___.

   Does the applicant's device transmit data 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 _____

   By review of the software validation report, the sponsor has demonstrated that the device was designed and developed according to principles of good software life-cycle processes.

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:

1. Infection Control Studies: The PRECICHEK Cloudia Blood Glucose meter is intended for single-patient use only. Virucide efficacy testing was performed by an outside commercial testing service using Hepatitis B surface antigen (HBsAg) demonstrating disinfection efficacy with Clorox Germicidal Wipes (EPA Reg No.67619-12) and the materials comprising the meter. The sponsor also conducted robustness studies and demonstrated that there was no change in the performance or the external materials for the meter after 18,250 cleaning and disinfection cycles to simulate 5 years of single-patient use by lay-users. Each robustness cycle consisted of one pre-clean wipe and one disinfecting wipe. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

2. The effect of hematocrit levels was evaluated using specimens at 6 glucose concentrations within the following ranges: 20-50, 51-110, 111-150, 151-250, 251-400, 401-600 mg/dL. Each concentration was tested in replicates of 6 under the following hematocrit levels: 25, 30, 35, 45, 55, 65%. The study incorporated 6 glucose meters. Blood analysis was also performed on the YSI 2300 glucose analyzer. The percent bias relative to YSI was calculated for each individual result. The study supports the sponsor's claimed hematocrit range of 30-55%.

3. The effect of altitude was evaluated at the following elevations: sea level, 2000, 4000, 6000, 8800, and 10,000 feet, using venous whole blood specimens at 6 concentration levels: 30-50, 51-110, 111-150, 151-250, 251-400, 401-600 mg/dL. The specimens were tested on 3 lots of test strips with 10 meters in replicates of 10. Measurements were also taken on the YSI 2300 glucose analyzer. The percent bias was calculated for each individual specimen concentration. The study supports the sponsor's claimed maximum altitude of 8800 feet.

4. The effect of temperature and humidity were evaluated using venous whole blood specimens at 6 concentration levels: 30-50, 51-110, 111-150, 151-250, 251-400, 401-600 mg/dL. The specimens were tested on 2 lots of test strips with 5 meters in replicates of 2. The following temperature and humidity levels were evaluated: 10 C/20% RH, 15 C/30 RH, 20 C/45% RH, 25 C/55% RH, 35 C/70% RH, 40 C/80% RH, 10 C/80% RH, 15 C/70% RH, 20 C/55% RH, 25 C/45% RH, 35 C/30% RH, 40 C/20%. Measurements were also taken on the YSI 2300 glucose analyzer. The percent bias relative to YSI was calculated for each individual result. The study supports the sponsor claimed temperature range of 10-30 $^{\circ}$C, and claimed humidity range of 20-80%.

5. The effect of sample volume was evaluated using venous whole blood specimens at 6 concentrations levels: 30-50, 51-110, 111-150, 151-250, 251-400, 401-600 mg/dL. The specimens were tested on 3 lots of test strips with 3 meters in replicates of 9. For each concentration, 7 sample volumes -ranging from 0.3 – 0.7 µL in increments of 0.05- were evaluated. Blood glucose results obtained by the PRECICHEK meter were compared with those obtained by YSI. The percent bias relative to YSI was calculated for each individual result. The study supports the sponsor's claimed minimum sample volume of 0.5 µL.

6. Electromagnetic compatibility (EMC) (radiated emissions and immunity) testing was performed for the PRECICHEK Cloudia Blood Glucose Monitoring System. A signed technical compliance statement was provided to demonstrate that the EMC testing was performed according to listed standards in the test report. The test report indicates that the device is technically compliant with the requirements of the listed standards.

7. A readability assessment was performed whereby lay-users were instructed to evaluate the labeling and complete a questionnaire to gauge their comprehension of the labeling. According to the scoring, which rated the user's experience as a percentage of agreement with the survey statements from 0 – 100%, more than 85% of the lay-users scored 75% or better. A Flesh-Kincaid analysis was conducted, yielding the following results:

Labeling	Flesh-Kincaid Grade Level Score
User's Manual	7.9
Test Strip Insert	7.8
Control Solution Insert	7.7

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.