Food and Drug Administration
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I 510(k) Number:

K182428

II Applicant:

HMD BioMedical Inc.

III Proprietary and Established Names:

GlucoLeader Enhance Blood Glucose Monitoring System

IV Regulatory Information:

Product Code(s)	Classification	Regulation Section	Panel
NBW	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

V Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Glucose in fresh capillary whole blood samples obtained from the fingertip

C Type of Test:

Quantitative amperometric method (FAD - glucose dehydrogenase)

VI Intended Use/Indications for Use:

A Intended Use(s):

See Indication(s) for use below.

B Indication(s) for Use:

The GlucoLeader Enhance Blood Glucose Monitoring System is comprised of the GlucoLeader Enhance Blood Glucose Meter and GlucoLeader Enhance Blood Glucose Test Strips. The GlucoLeader Enhance Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The GlucoLeader Enhance Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It 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 GlucoLeader Enhance Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. GlucoLeader Enhance Blood Glucose Monitoring System is not for use in neonates.

C Special Conditions for Use Statement(s):

- OTC - Over The Counter
- This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long- term care facilities because it has not been cleared by FDA for use in these settings, including routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other blood borne pathogens.
- For single-patient use only.
- For self-testing.
- Use only fresh capillary whole blood from the fingertip.
- The device should not be used for the diagnosis or screening for diabetes.
- Do not use neonate blood sample.
- This device should not be used to test critically ill or hypotensive patients.
- Not for use in hypotensive individuals.
- Hematocrit level less than 10% may cause incorrect high readings and hematocrite levels greater than 70% may cause incorrect low readings.
- Altitudes above 10,000 feet (3,048 m) may cause inaccurate results.
- Extreme humidity may afffect the results. A relative humidity greater than 90% may cause incorrect results.
- The system is designed to be used at temperatures between 46.4°F to 111.2°F (8°C to 44°C). Outside this range, the system may yield erroneous results.
- Severe dehydration or excessive water loss may cause false, high results.

D Special Instrument Requirements:

GlucoLeader Enhance Blood Glucose Meter.

VII Device/System Characteristics:

A Device Description:

The GlucoLeader Enhance Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood. The GlucoLeader Enhance Blood Glucose Monitoring System consists of the following: GlucoLeader Enhance Blood Glucose Meter; Lancets and lancing device; GlucoLeader Enhance Blood Glucose Test Strips; GlucoLeader Enhance Glucose Control Solutions (L1: low glucose level, L2: high glucose level) and GlucoLeader Enhance Check Strip. GlucoLeader Enhance Blood Glucose Test Strips and GlucoLeader Enhance Glucose Control Solutions are not included in the kit package and should be purchased separately.

B Principle of Operation:

The GlucoLeader Enhance Blood Glucose Monitoring System measures glucose using an amperometric detection method. The reaction of glucose dehydrogenase (FAD-GDH) and an electron mediator in the GlucoLeader Enhance test strip with glucose in the whole blood sample from the fingertip produces an electrical current that is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration, calibrated to plasma reference, which is displayed by the meter.

C Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☐	☒
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:	☒	☐

1. Instrument Name:

   GlucoLeader Enhance Blood Glucose Monitoring System

2. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

3. Specimen Sampling and Handling:

   The glucose test is intended to be used with capillary whole blood from the finger. The whole blood sample is applied directly to the test strip by capillary action.

4. Calibration:

   The meter requires calibration or coding by the user. When using the meter for the first time, or when opening a new vial of test strips, the code number indicated on the new test strip vial will need to be set by pressing a button to obtain the code number indicated on the new test strip vial.

5. Quality Control:

   GlucoLeader Enhance Control Solutions are aqueous solutions containing glucose and are available at two levels (L1: low glucose level; L2: high glucose level). Instructions on how to order control solutions, and when to perform a control solution test are included in the user guide. The user is cautioned not to use the meter and to contact the customer support if the control result falls outside these ranges the range printed on the test strip bottle label.

VIII Substantial Equivalence Information:

A Predicate Device Name(s):

Glucoleader Enhance Self-monitoring Of Blood Glucose System

B Predicate 510(k) Number(s):

K032985

C Comparison with Predicate:

Device & Predicate Device(s):	K182428	K032985
General Device Characteristic Similarities		
Intended Use/Indications For Use	The GlucoLeader Enhance Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertip as an aid to monitor the effectiveness of diabetes control.	Same

Intended use population	Single-patient use	Same
Detection method	Amperometric glucose biosensor	Same
General Device Characteristic Differences		
Methodology	Glucose Dehydrogenase-FAD (GDH-FAD)	Glucose Oxidase (GOD)
Hematocrit range	10-70%	30-50%
Strip reaction time	5 seconds	15 seconds
Sample volume	0.8 µL	3.0 µL
Measurement range	10-600 mg/dL	30-600 mg/dL
System operating conditions	46.4-111.2 °F (8-44 °C) 10%-90% R.H.	50.0-104.0 °F (10-40 °C) 20-80% R.H.
Data memory/Recall	800 test results	180 test results

IX Standards/Guidance Documents Referenced:

FDA Guidance Document; Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use, issued on October 11, 2016

IEC 61010-1:2010, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements.

IEC 60601-1-2: 2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

CLSI, EP6-A: 2003, Evaluation of the linearity of quantitative analytical Methods: A Statistical Approach.

CLSI EP7-A2: 2005, Interference Testing in Clinical Chemistry, Approved Guideline, 2nd Edition.

X Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   Within-run precision studies were performed using venous whole blood samples adjusted to five glucose concentration levels as determined by the comparator method YSI 2300: 30-50, 51-110, 111-150, 151-250 and 251-400 mg/dL. Each glucose level was analyzed in replicates

of 10, using 3 lots of test strips and 10 meters for a total of 300 measurements per each glucose level. Results are summarized below:

Glucose Level (mg/dl)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level I (30-50)	1	100	42.6	1.8	4.2
	2	100	47.8	2.4	5.0
	3	100	46.7	2.0	4.2
	Combined	300	45.7	2.1	4.6
Level II (51-110)	1	100	81.0	2.8	3.4
	2	100	85.4	3.5	4.1
	3	100	81.5	2.2	2.6
	Combined	300	82.6	2.9	3.5
Level III (111-150)	1	100	129.7	4.1	3.2
	2	100	130.8	4.9	3.8
	3	100	130.6	4.0	3.0
	Combined	300	130.4	4.4	3.3
Level IV (151-250)	1	100	172.9	6.2	3.6
	2	100	174.6	6.4	3.7
	3	100	172.0	6.2	3.6
	Combined	300	173.2	6.3	3.6
Level V (251-400)	1	100	274.3	11.3	4.1
	2	100	274.9	11.6	4.2
	3	100	276.7	10.4	3.8
	Combined	300	275.3	11.1	4.0

Intermediate (day-to-day) precision was evaluated using 5 levels of glucose control solutions with concentrations of approximately 45, 80, 125, 200 and 300 mg/dL as determined by the comparator method YSI 2300. For each concentration, 10 measurements were taken over 10 days using 10 meters and 3 lots of test strips, for a total of 300 measurements per sample. Results are summarized below:

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level I (30-50)	1	100	43.1	1.1	2.6
	2	100	44.3	1.2	2.7
	3	100	43.8	1.4	3.2
	Combined	300	43.7	1.2	2.8
Level II (51-110)	1	100	79.4	1.7	2.2
	2	100	80.0	1.7	2.2
	3	100	80.2	2.7	3.3
	Combined	300	79.9	2.1	2.6
Level III (111-150)	1	100	129.6	2.7	2.0
	2	100	129.8	2.8	2.2
	3	100	130.0	2.6	2.0
	Combined	300	129.8	2.7	2.1
Level IV	1	100	202.0	3.2	1.6

Glucose Level (mg/dL)	Lot	N	Mean (mg/dL)	SD (mg/dL)	CV (%)
(151-250)	2	100	202.7	3.6	1.8
	3	100	202.6	3.7	1.8
	Combined	300	202.4	3.5	1.7
Level V (251-400)	1	100	302.0	5.3	1.8
	2	100	300.8	5.6	1.9
	3	100	305.4	6.7	2.2
	Combined	300	302.7	5.9	1.9

2. Linearity:
Linearity was evaluated using 13 levels of venous whole blood glucose concentrations (9.2, 23.4, 40.8, 63.8, 85.8, 119.0, 179.0, 237.0, 281.0 350.0, 454.0, 538.0 and 609.0 mg/dL) as determined by the comparator method YSI 2300. Each glucose level was measured in replicates of 20 using 2 glucose meters and 3 lots of test strips, and the values from the GlucoLeader Enhance meter were compared to the values obtained from the comparator method, YSI 2300. Linear regression analysis of the results yielded the following:

Test strip lot 1: $y = 0.9836 x + 2.2189$ $R^2 = 0.9972$
Test strip lot 2: $y = 0.9814 x + 3.5638$ $R^2 = 0.9968$
Test strip lot 3: $y = 1.0061 x + 1.4702$ $R^2 = 0.9966$

The results of the linearity study support the sponsor's claimed glucose measurement range of 10- 600 mg/dL. If a sample is less than 10 mg/dL glucose, the result is flagged by the meter as "Lo". If a sample exceeds 600 mg/dL glucose, the result is flagged by the meter as "Hi". The "Lo" and "Hi" functions were validated and demonstrated to function as intended.

3. Analytical Specificity/Interference:
To assess potential interferences, a study was conducted using venous whole blood samples adjusted to the following glucose levels as measured by the comparator method, YSI 2300: 50-70, 110-130 and 225-270 mg/dL. Each of these samples was divided into a test pool and a control pool, with each of the potential endogenous and exogenous interfering substances added to the test pool. The study used 3 lots of test strips and 10 meters, for a total of 30 replicates per test sample. The difference between test sample and control sample meter results was calculated. The table below shows the highest concentration of substance tested at which no significant interference (as defined by the sponsor as ± 10 mg/dL for glucose concentrations < 100 mg/dL and ± 10% for glucose concentrations > 100 mg/dL) was observed:

Potential Interfering Substance	Highest Concentration without Significant Interference (mg/dL)
Acetaminophen*	< 5
Ascorbic Acid	3
Unconjugated Bilirubin	20
Conjugated Bilirubin	25
Cholesterol	500
Creatinine	10

Potential Interfering Substance	Highest Concentration without Significant Interference (mg/dL)
Dopamine	2.5
EDTA	200
Galactose	15
Gentisic Acid	1.875
Reduced Glutathione	23
Hemoglobin	2500
Heparin	3000
Ibuprofen	50
Icodextrin	1094.4
L-Dopa	0.5
Maltose	625
Methyldopa	3.13
Salicylic Acid	60
Sodium	610
Tolbutamide	100
Tolazamide	4.7
Triglycerides	750
Uric Acid	12
Xylose	200
Sugar Alcohols	0.09

*Significant interference was observed at acetaminophen concentrations of 5 mg/dL.

The sponsor has included the following in the labeling (user manual):

- Do not use this device while taking acetaminophen or acetaminophen-containing drugs (such as Tylenol, certain cold and flu remedies or certain prescription drugs). You may receive incorrect meter results if you have recently taken any acetaminophen.
- If you have a disease or condition that elevated your blood uric acid level (> 12 mg/dL), such as gout, your blood glucose results may not be reliable. If you are unsure, then ask your doctor.
- If you are taking high doses of vitamin C (ascorbic acid in your blood concentration > 3 mg/dL), your blood glucose results using this meter may not be reliable.
- If you are taking high doses of Tolazamide (blood concentration > 4.7 mg/dL), your blood glucose results using this meter may not be reliable.

4. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The GlucoLeader Enhance Blood Glucose Monitoring System is traceable to the NIST (SRM) 917A. A method comparison was performed using the candidate device and YSI 2300 as the reference method. The meter provides plasma-equivalent results.

Test Strip Stability

Test strip stability was assessed using real-time stability studies. Testing protocols and acceptance criteria were reviewed and found to be acceptable. The sponsor claims a shelf life

stability of 24 months and an open vial stability of 90 days at the recommended storage conditions of 35.6-85.9°F (2-30°C) and relative humidity (RH) of 10%-90%.

5. Detection Limit:

   The reportable range is 10 to 600 mg/dL based on linearity studies above (A2).

6. Assay Cut-Off:

   Not applicable.

7. Accuracy (Instrument):

   Not applicable.

8. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See lay user study below in section C3.

2. Matrix Comparison:

   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   To assess the performance of GlucoLeader Enhance Test System in the hands of the intended users, the sponsor performed a study with 360 lay-user participants. The users were responsible for obtaining their own fingertip capillary sample and performing a blood glucose test according to the instructions in the user's guide and quick guide. A total of 6 GlucoLeader Enhance meters and 3 lots of GlucoLeader Enhance Blood Glucose Test Strip were used. Results were analyzed by comparing the blood glucose results obtained by the lay users with the GlucoLeader Enhance Test System against results obtained with the laboratory-based comparator method (YSI 2300 glucose analyzer). The glucose

concentrations in the samples ranged between 37.6-439.6 mg/dL, as measured by the YSI 2300. The set included 47 native samples with glucose concentration < 80 mg/dL and 49 samples with glucose concentration > 250 mg/dL. The results for the first lot vs. YSI 2300 are summarized below:

Glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
26/44 (59.1%)	38/44 (86.4%)	43/44 (97.7%)	44/44 (100.0%)

Glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
189/316 (59.8%)	267/316 (84.5%)	308/316 (97.5%)	316/316 (100.0%)

Combined glucose concentrations across the measuring range:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
215/360 (59.7%)	305/360 (84.7%)	351/360 (97.5%)	360/360 (100.0%)

Results of the linear regression analysis:

Slope	Y-intercept	R^2
1.0325	-3.6101	0.9791

A Flesch-Kincaid readability assessment was conducted, and the results demonstrate that the User Guide, Test Strip Insert and Quick Guide Instructions were written at an 8th grade level or less.

Accuracy at extreme glucose values:

To further assess the performance of the GlucoLeader Enhance Test System at the extreme upper and lower ends of the claimed measuring range, the sponsor altered 100 capillary whole blood samples, by spiking or allowing samples to glycolyse, to achieve glucose concentrations below 80 mg/dL (50 samples; 9 – 75 mg/dL according to YSI 2300) and above 250 mg/dL (50 samples; 262 - 604 mg/dL according to YSI 2300). Samples were compared the comparator method, YSI 2300. The results for one representative lot are summarized below:

Glucose concentrations < 80 mg/dL:

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	Within ± 20 mg/dL
31/50 (62.0%)	46/50 (92.0%)	49/50 (98.0%)	50/50 (100.0%)

Glucose concentrations > 250 mg/dL:

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
33/50 (66.0%)	43/50 (86.0%)	49/50 (98.0%)	50/50 (100.0%)

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

The labeling includes the following expected glucose values for people without diabetes:

Time of day	People without diabetes
Fasting and before meals	< 100 mg/dL
2 hours after meals	< 140 mg/dL

Source: American Diabetes Association, Standard of Medical Care in Diabetes 2019, Vol. 39.

F Other Supportive Instrument Performance Characteristics Data:

1) Hematocrit Study:
The GlucoLeader Enhance Blood Glucose Meter System was assessed at 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65% and 70% hematocrit levels, and at 5 glucose concentrations (30-50, 51-110, 111-150, 151-250 and 251-400 mg/dL). Each sample was tested in replicates of 10 using 5 meters and 3 lots of test strips, for a total of 30 replicates per sample. The values were compared with the glucose measurements obtained from YSI 2300 comparator method. The % bias of the GlucoLeader Enhance Blood Glucose Meter System relative to YSI 2300 demonstrated adequate performance to support the claimed hematocrit range of 10-70%.

2) Altitude study:
To assess the effect of altitude, venous whole blood samples adjusted to 5 glucose concentrations covering the measuring range (39, 85, 179, 311 and 529 mg/dL) were tested at sea level (7 feet) and at an elevation of 10,355 feet in replicates of 5, using 4 GlucoLeader Enhance Blood Glucose Meters and 1 lot of test strips, for a total of 20 replicates per samples). Values measured by the candidate device were compared to the comparator method YSI 2300. The results support the claim that the GlucoLeader Enhance Blood Glucose Monitoring System can be operated at altitudes of up to 10,000 ft.

3) Operating conditions (temperature, humidity):
The GlucoLeader Enhance Blood Glucose Monitoring System was tested at different temperature and humidity conditions to assess the effect of operation environment on the meter's performance. Temperatures ranging from 46.4°F – 111.2°F (8-44°C) and relative humidity from 10% to 90% were tested. Meter results were compared to the YSI 2300

comparator analyzer. Four temperature and humidity combinations were tested including low temperature/low humidity, low temperature/high humidity, high temperature/low humidity and high temperature/high humidity. Each of 4 venous whole blood glucose levels (20-50; 111-150; 251-400 and 401-600 mg/dL) were tested in replicates of 5 by 2 meters, for a total of 10 replicates per sample. Values measured by the GlucoLeader Enhance Blood Glucose Monitoring System were compared to the comparator method YSI 2300 analyzer. The study results support the operating condition claim of 46.4-111.2°F (8-44°C) and 10-90% RH.

4) Sample volume study:
To verify the test strip minimum sample volume requirement (0.8 µL), venous whole blood samples with glucose concentrations levels the following levels were used: 50-65 mg/dL, 100-120 mg/dL and 200-250 mg/dL. Sample volumes of 0.45, 0.50, 0.60, 0.70, and 0.80 µL were tested using 3 lots of test strips for a total of 9 measurements per sample volume per glucose level. Values obtained with the candidate device were compared to values obtained using the comparator method (YSI 2300). Results support the claimed minimum sample volume of 0.8 µL. When the sample volume is lower than 0.80 µL the meter does not provide a result and displays an error code, therefore the sample detection feature functions appropriately when the sample volume is insufficient.

5) Intermittent sampling, sample perturbation and testing with used test strips:
Intermittent sampling, sample perturbation, and testing with used test strips testing was completed by the sponsor. The testing performed demonstrated that the GlucoLeader Enhance Blood Glucose Monitoring System is robust to intermittent sampling, sample perturbation, and that an error message is returned to the user if a used test strip is inserted into the meter.

6) EMC
The sponsor provided documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed and the system was found to be compliant.

7) Cleaning and disinfection robustness evaluation (Infection control studies)
The device is intended for a single-patient use only. Disinfection efficacy studies were performed on the materials the comprising the meter by an outside commercial testing laboratory, demonstrating removal of the HBsAg antigen with the chosen disinfectant, Clorox Germicidal Wipes (EPA Registration Number 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter. The robustness studies were designed to simulate cleaning and disinfection procedures 10 times a day for 5 years (a total of 18,250 cycles of cleaning and disinfection). Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

8) Test strip lot release criteria

The test strip lot release protocols and criteria were reviewed and found to be acceptable.

XI Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

XII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.