



May 8, 2019

HMD BioMedical Inc.  
% Ke-Min Jen  
Chinese-European Industrial Research Society  
No. 58 Fu-Chiun St.  
Hsin-Chu City, 30067  
Taiwan

Re: K182428

Trade/Device Name: GlucoLeader Enhance Blood Glucose Monitoring System  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: Class II  
Product Code: NBW  
Dated: March 31, 2019  
Received: April 8, 2019

Dear Ke-Min Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm, Ph.D.  
Acting Director  
Division of Chemistry  
and Toxicology Devices  
OHT7: Office of In Vitro Diagnostics  
and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

k182428

Device Name

GlucoLeader Enhance Blood Glucose Monitoring System

Indications for Use (Describe)

The GlucoLeader Enhance Blood Glucose Monitoring System is comprised of 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**5. 510(K) Summary of Safety and Effectiveness** (Per 21 CFR 807.92)

**510(k) number K182428**

Type of 510(k) Submission Traditional

Basis for the submission A New Device

Common Name of the Proposed Device GLUCOSE TEST SYSTEM

Trade name GlucoLeader Enhance Blood Glucose Monitoring System

510(k) Submitter HMD BioMedical, Inc.

Address: No. 181, Minsheng St., Xintpu Township, Hsinchu County, Taiwan 30542

Phone: 886-3-5895000, Fax: 886-3-5885500

Website: [www.hmdbio.com](http://www.hmdbio.com)

Registration Number: 3003902721

FEI Number: 3003902721

Date prepared **May 7, 2019**

Contact Person Dr. JEN, KE-MIN

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Classification Regulation SYSTEM, TEST, BLOOD GLUCOSE, OVER THE COUNTER (21 CFR 862.1345)

Class II

Panel Clinical Chemistry

Product Code NBW

Operator Number 9053177

Predicate Device

Manufacturer HMD BioMedical, Inc.

Device Name GlucoLeader Enhance Self-Monitoring of Blood Glucose System

510(k) Number K032985



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### ● **Intended Use:**

The GlucoLeader Enhance Blood Glucose Monitoring System is comprised of 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.

### ● **Device Description:**

The GlucoLeader Enhance Blood Glucose Monitoring System is designed to pursue the accuracy in blood glucose monitoring to provide you with easy and comfortable testing. The GlucoLeader Enhance Blood Glucose Monitoring System mainly consists of four parts as below,

- 1) GlucoLeader Enhance Blood Glucose Meter
- 2) GlucoLeader Enhance Blood Glucose Test Strips\*
- 3) GlucoLeader Enhance Glucose Control Solutions (L1-Low glucose level, L2-High glucose level)\*
- 4) GlucoLeader Enhance Check Strip\*.

\*These products are intended to be used together to get accurate blood glucose test results. They are not included in the kit package, and should be purchased separately.

The meter display screen size of 1.73" x 1.7" is large and easy-to-read, and the meter weight of 0.122 lbs. (55.2 grams) is lightweight and portable for your convenience. The GlucoLeader Enhance Blood Glucose Monitoring System is traceable to the NIST (SRM) 917A. The GlucoLeader Enhance Glucose Control Solutions have L1 and L2 levels for optional purchasing, and L1 is low glucose level and L2 is high glucose level.

The GlucoLeader Enhance Blood Glucose Meter has the latest technology for blood glucose monitoring and is made with quality components. The GlucoLeader Enhance Blood Glucose Test Strips have been updated with Glucose dehydrogenase-FAD Enzyme, which not only improves the accuracy of measurements, but also increases the HCT interference range up to 10-70%. Also, the required test blood sample



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volume is reduced to 0.8  $\mu$ L, and the test reaction time is only 5 seconds.

If your GlucoLeader Enhance Blood Glucose Meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be disinfected prior to use by the second person. Consult your healthcare professional if unusual readings occur.

### ● Test Principle

Blood glucose is measured by an electrical current that is produced when a blood sample mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample. The meters measure the strength of the electrical current, calculate your blood glucose level and then display your result in either default unit mg/dL or mmol/L. The GlucoLeader Enhance Blood Glucose Meter, GlucoLeader Enhance Blood Glucose Test Strips and GlucoLeader Enhance Glucose Control Solutions have been designed, tested and proven to work together as a system to produce accurate blood glucose concentration test results.

### ● Comparison Table

Comparison Items	Predicate device	Subject device
Manufacturer	HMD BioMedical, Inc.	HMD BioMedical, Inc.
Trade Name	GlucoLeader Enhance Self-Monitoring of Blood Glucose System	GlucoLeader Enhance Blood Glucose Monitoring System
Product Code	NBW	NBW
510(k) Number	K032985	K182428
Indications for use	The GlucoLeader Enhance Self-Monitoring of Blood Glucose 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	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.

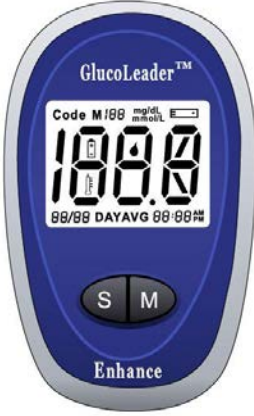

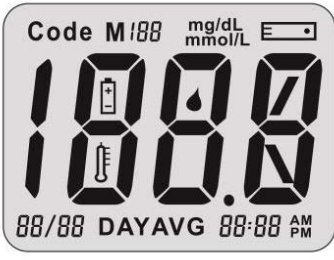



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	control.	
<b>Meter differences</b>		
<b>Meter Appearance</b>		
<b>LCD screen and display size</b>	 size: 1.61“(L) x 1.48” (W)	 Size: 1.73”(L) x 1.77”(W)
<b>Meter dimension (LxWxH)</b>	3.78” x 2.36” x 0.73”	3.81” x 2.36”x 0.65”
<b>Meter weight (with battery)</b>	0.154 lbs. (70.0 g)	0.122 lbs. (55.2g)
<b>Reaction time</b>	15 seconds	5 seconds
<b>Data memory / Recall</b>	Storing 180 test results	Storing 800 test results
<b>System operating environment</b>	50.0 °F -104.0 °F (10 °C-40 °C) 20% - 80% R.H.	46.4 °F -111.2 °F (8 °C-44 °C) 10% - 90% R.H.
<b>Meter storage environment</b>	50.0 °F -104.0 °F (10 °C-40 °C) 20% - 80% R.H.	-13.0 °F -158.0 °F (-25 °C - 70 °C ) 10% - 90% R.H.
<b>Measuring range</b>	30 -600 mg/dL (1.66 – 33.3 mmol/L)	10 - 600 mg/dL (0.6 to 33.3 mmol/L)
<b>Meter similarities</b>		
<b>Methodology</b>	Amperometry glucose biosensor	Same
<b>Memory button</b>	Press Mem button to enter memory mode to recall the information	Same





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	stored in meter's memory	
<b>Set button</b>	Press Set button to enter date and time setting	Same
<b>Measuring unit</b>	mg/dL (mmol/L)	Same
<b>Resolution</b>	1 mg/dL LCD display	Same
<b>Meter precision</b>	Circuit imprecision CV < 5%	Same
<b>Meter electrical accuracy</b>	Tested with standard resistor the bias < ±2%	Same
<b>Code-checking mechanism</b>	Code number checking	Same
<b>Temperature compensation mechanism</b>	Automatic compensation with built-in thermistor	Same
<b>Power source</b>	One Lithium battery ( 3V, CR2032)	Same
<b>Power saving</b>	Automatic shut-off in 3-minute idle	Same
<b>Battery operation life</b>	More than 1000 times test	Same
<b>Strip Differences</b>		
<b>Test strips appearance</b>	 Dimensions: 1.46"X 0.24" x 0.02"	 Different Appearance but has the same dimensions
<b>Enzyme</b>	Glucose Oxidase (GOD)	Glucose Dehydrogenase-FAD (GDH-FAD)
<b>Minimum sample volume</b>	3.0 µL	0.8 µL
<b>HCT range</b>	30 - 50%	10 - 70%
<b>System operating environment</b>	50.0 °F~104.0 °F (10°C~40°C), 20% ~ 80% R.H.	46.4 °F~111.2 °F (8 °C~44 °C), 10% - 90% R.H.
<b>Strip Storage Environment</b>	50.0 °F~104.0 °F (10 °C~40 °C), 20% ~ 80% R.H.	35.6 °F~ 86.0 °F (2°C~30°C), 10% - 90% R.H.
<b>Reaction time</b>	15 seconds	5 seconds
<b>Strip similarities</b>		
<b>Methodology</b>	Amperometry glucose biosensor	Same
<b>Type of blood drawing</b>	Two sides	Same
<b>Strip precision</b>	Imprecision CV < 5%	Same
<b>Strip dimension</b>	1.46"X 0.24" x 0.02"	Same
<b>Specimen</b>	Capillary whole blood from fingertip	Same



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<b>Shelf life</b>	24 months for closed vial of test strips 90 days after first opening cap of test strips vial	Same
<b>Compliant Electrical Safety &amp; EMC standards</b>	<p><b>EMC:</b> EN 60601-1-2:2007+AC:2010 IEC 61326-1:2006 IEC 61326-2-6:2005</p> <p><b>Electrical Safety:</b> EN 61010-1:2001 EN 61010-2-101:2002</p>	<p><b>EMC:</b> IEC 60601-1-2:2007* IEC 61326-1:2012 IEC 61326-2-6:2012 47 CFR FCC Part 15 Subpart B</p> <p><b>Electrical Safety:</b> IEC 61010-1:2010** IEC 61010-2-101:2015</p> <p><i>*It is recognized by FDA as 19-1.</i> <i>**It is recognized by FDA as 19-18.</i></p>

● **Substantial Equivalence Discussions**

A claim of substantial equivalence is made to GlucoLeader Enhance Self-Monitoring of Blood Glucose System (k032985). Both of them have the similar indications for use, the same working principle, technologies and detection method. The minor differences for the two devices are LCD screen size, meter dimensions, meter weight, reaction time, data memory, meter storage environment, measuring range, enzyme, minimum sample volume, strip accuracy, HCT range, system operating environment, and strip storage environment,

The GlucoLeader Enhance Blood Glucose Test Strips have been updated with Glucose Dehydrogenase-FAD Enzyme, which not only improves the accuracy to the standard, but also increases the HCT interference range up to 10-70%. The test required blood sample volume reduced to 0.8 µL, and the test reaction time is only 5 seconds

Most of these differences have been validated through the respective non-clinical and clinical testing to indicate there are no any new safety and effectiveness concerns raised. Besides, the subject device and predicate device have the similar intended for use in the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingers. Thus the differences are shown to be due to the feature design aspects, not to raise any new safety or effectiveness concerns.

The conclusions drawn from the non-clinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.



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## ● Summary of performance tests

### ■ Altitude study:

The changes of altitude from sea level to 10,000 feet (3048 meters) appear no significant effect on the glucose measurements of the GlucoLeader Enhance Blood Glucose Monitoring System. The test results of one lot of test strip show that bias and bias% of five glucose measures at each attitude level are within the acceptance criteria of the glucose difference within  $\pm 10\%$ .

### ■ Hematocrit interference study:

GlucoLeader Enhance Blood Glucose Monitoring System is capable of precise measurement with 5 intervals of blood glucose concentrations and with hematocrit range from 10% to 70%. The Glucose differences are within  $\pm 8\%$  and no individual value differences  $\pm 15\%$  relative to the YSI, at HCT levels from 10% to 70% when glucose concentrations are  $\square 75$  mg/dL. The Glucose differences are within  $\pm 15$  mg/dL when glucose concentrations are  $< 75$ mg/dL. The test results of hematocrit effect are verdict “**Accept**” at HCT levels from 10% to 70%.

### ■ Interference substances evaluation:

This evaluation was conducted under the directions of Guideline of FDA October 11, 2016 “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use” and CLSI EP7-A2. According to this study, evaluating 26 endogenous and exogenous substances in venous blood samples with 3 different levels of glucose concentrations, split into a control sample and a test sample. The % difference between the test and control sample was calculated. The highest concentration tested at which no significant interference was summarized as below.

A sample with large amount of reducing substances such as Acetaminophen ( $>5$ mg/dL), Unconjugated Bilirubin ( $>20$ mg/dL), Conjugated Bilirubin ( $>25$ mg/dL), Dopamine ( $>2.5$ mg/dL), Genticic acid ( $>1.875$ mg/dL), Reduced Glutathione ( $>23$ mg/dL), Hemoglobin ( $>2500$ mg/dL), Maltose ( $>625$ mg/dL), Methyldopa ( $>3.13$ mg/dL), Sodium ( $>610$ mg/dL), Tolazamide ( $>4.7$ mg/dL), Triglycerides ( $>750$ mg/dL), Uric acid ( $>12$ mg/dL) may cause the result slightly higher than the actual glucose level.

### ■ Within –run precision evaluation:

The evaluation was conducted according to the Guideline of FDA October 11, 2016 Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use.



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The within-run precision evaluation results of GlucoLeader Enhance Blood Glucose Monitoring System meet the American Diabetes Association acceptance criteria, i.e., **CV within 5%** at glucose concentration  $\geq 100$  mg/dL and **SD within 5 mg/dL** at glucose concentration  $< 100$  mg/dL. The summary table of within-run precision test by Lot 1 for 100 samples is shown as below. The test results meet the acceptance criteria and GlucoLeader Enhance Blood Glucose Monitoring System passes the within-run precision evaluation.

**Data Summary of the within-run precision test results**

Glucose level	Lot	Standard YSI Glucose concentration (mg/dL)	SD (mg/dL)	CV%
<b>1</b>	<b>1</b>	<b>43.2</b>	<b>1.8</b>	4.2%
	<b>2</b>		<b>2.4</b>	5.0%
	<b>3</b>		<b>2.0</b>	4.2%
	<b>Combined</b>		<b>2.1</b>	4.6%
<b>2</b>	<b>1</b>	<b>80.7</b>	<b>2.8</b>	3.4%
	<b>2</b>		<b>3.5</b>	4.1%
	<b>3</b>		<b>2.2</b>	2.6%
	<b>Combined</b>		<b>2.9</b>	3.5%
<b>3</b>	<b>1</b>	<b>138.3</b>	4.1	<b>3.2%</b>
	<b>2</b>		4.9	<b>3.8%</b>
	<b>3</b>		4.0	<b>3.0%</b>
	<b>Combined</b>		4.4	<b>3.3%</b>
<b>4</b>	<b>1</b>	<b>178.5</b>	6.2	<b>3.6%</b>
	<b>2</b>		6.4	<b>3.7%</b>
	<b>3</b>		6.2	<b>3.6%</b>
	<b>Combined</b>		6.3	<b>3.6%</b>
<b>5</b>	<b>1</b>	<b>278.3</b>	11.3	<b>4.1%</b>
	<b>2</b>		11.6	<b>4.2%</b>
	<b>3</b>		10.4	<b>3.8%</b>
	<b>Combined</b>		11.1	<b>4.0%</b>



■ **Intermediate precision (day-to-day) evaluation**

The Intermediate (day-to-day) precision evaluation results of GlucoLeader Enhance Blood Glucose Monitoring System are shown in the following table. The criteria is the **CV** of the glucose devices must be less than **5 %** when the concentration is  $\geq 100$  mg/dL, and **SD** must be less than **5 mg/dL** when the concentration is  $<100$  mg/dL. Compared to the criteria, it is concluded that the subject device passes the intermediate precision evaluation.

**Data Summary of the intermediate precision results**

Glucose level	Lot	Standard YSI glucose concentration (mg/dL)	SD (mg/dL)	CV%
<b>1</b>	<b>1</b>	<b>45.0</b>	<b>1.1</b>	2.6
	<b>2</b>		<b>1.2</b>	2.7
	<b>3</b>		<b>1.4</b>	3.2
	<b>Combined</b>		<b>1.2</b>	2.8
<b>2</b>	<b>1</b>	<b>80.0</b>	<b>1.7</b>	2.2
	<b>2</b>		<b>1.7</b>	2.2
	<b>3</b>		<b>2.7</b>	3.3
	<b>Combined</b>		<b>2.1</b>	2.6
<b>3</b>	<b>1</b>	<b>125.0</b>	2.7	<b>2.0</b>
	<b>2</b>		2.8	<b>2.2</b>
	<b>3</b>		2.6	<b>2.0</b>
	<b>Combined</b>		2.7	<b>2.1</b>
<b>4</b>	<b>1</b>	<b>200.0</b>	3.2	<b>1.6</b>
	<b>2</b>		3.6	<b>1.8</b>
	<b>3</b>		3.7	<b>1.8</b>
	<b>Combined</b>		3.5	<b>1.7</b>
<b>5</b>	<b>1</b>	<b>300.0</b>	5.3	<b>1.8</b>
	<b>2</b>		5.6	<b>1.9</b>
	<b>3</b>		6.7	<b>2.2</b>
	<b>Combined</b>		5.9	<b>1.9</b>



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■ **Linearity evaluation:**

Linearity evaluation are conducted under the directions of **CLSI EP6-A**, and the results show the correlation coefficient is 1.00, The linearity range of GlucoLeader Enhance Blood Glucose Monitoring System is **10 – 600 mg/dL**.

■ **Sample perturbation study:**

Sample perturbation occurs when a user has applied an appropriate volume of blood to the test strip for glucose measurement but an event such as wicking of blood away from the test strip, flicking of the test strip or flicking of the meter occurs during the start of measurement. Under the directions of FDA Guideline of October 11, 2016 “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use” and CLSI EP7-A2, the results show the sampling perturbation has no significant effect on precise blood glucose measurement for GlucoLeader Enhance Blood Glucose Monitoring System.

■ **Sample volume evaluation:**

Under the directions **CLSI EP7-A2** and Guideline of FDA October 11, 2016 “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use” and CLSI EP7-A2, it is shown the sample volume of 0.8  $\mu$ L is the minimum sample volume to have accurate measurements. When the blood sample volume is less than 0.8 $\mu$ L reaction chamber of the test strip cannot be fully filled and the measurement will not start. The meter will automatically display the error code number E42.

■ **Stressed operating temperature and humidity evaluation:**

The stressed operating temperature and humidity evaluation results show the Bias are less than 10 mg/dL for glucose <100 mg/dL and Bias are less than 10 % for glucose  $\geq$  100 mg/dL. The test results meet the acceptance criteria. We declare that the GlucoLeader Enhance Blood Glucose Monitoring System can be operated normally under the conditions of 50-104 °F (10 ~ 40 °C), 10 ~ 90% RH.

■ **User performance clinical evaluation:**

This User performance evaluation was conducted under the directions of Guideline of FDA October 11, 2016 “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use”. The results of a study where 360 typical users used the GlucoLeader Enhance blood glucose meter to test their blood glucose level. The GlucoLeader Enhance blood glucose meter gave results within 15% of their true blood glucose level 351 out of 360 times. The summary of data



## Your Partner in Blood Glucose Monitoring

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for measurements performed by Lot 1 versus YSI 2300 shown below meets the acceptance criteria.

Within±5%	Within±10%	Within±15%	Within±20%
59.7% (215/360)	84.7% (305/360)	97.5% (351/360)	100% (360/360)

### ■ System accuracy evaluation at Extreme Glucose Values:

According to the results from the measurements of a total of 3 strip lots from 100 subjects at extreme glucose values, more than 95% of individual bias fell within ±15 mg/dL at blood glucose concentration < 75 mg/dL and more than 95% of individual bias fell within ±15% at blood glucose concentrations ≥75mg/dL. Therefore, the results meet the acceptance criteria.

Summary of data within mg/dL of the comparator method for glucose concentrations < 80 mg/dL: **(All Lots)**

Within +/- 5 mg/dL	Within +/- 10 mg/dL	Within +/- 15 mg/dL	Within +/- 20 mg/dL
97/150 (64.7%)	140/150 (93.3%)	148/150 (98.7%)	150/150 (100%)

Summary of data within % of the comparator method for glucose concentrations > 250 mg/dL: **(All Lots)**

Within +/- 5 %	Within +/- 10 %	Within +/- 15 %	Within +/- 20 %
101/150 (67.3%)	127/150 (84.7%)	146/150 (97.3%)	150/150 (100%)

### ■ Cleaning & disinfection robustness evaluation:

The physical appearance and performance checks on the GlucoLeader Enhance Blood Glucose Meters and lancing devices were capable for 18,250 times of cleanings and disinfections, which mimicked the regular use of a lay-user who used 10 times a day for 5 years. After 18,250 times of cleanings and disinfections, with no damaging and readable logo/labels on the GlucoLeader Enhance Blood Glucose meters and lancing devices. The performances of the GlucoLeader Enhance Blood Glucose meters and lancing devices worked properly with the stimulated test strip. These results concluded that with 5 years of regular uses for 10 times a day, i.e., 18,250 times of cleanings and disinfections, the appearance, performance, reading, and functionalities of the GlucoLeader Enhance Blood Glucose meters and lancing devices would not be affected.



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### ■ User performance clinical evaluation:

This User performance evaluation was conducted under the directions of Guideline of FDA October 11, 2016 “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use”. The results of a study where 360 typical users used the GlucoLeader Enhance blood glucose meter to test their blood glucose level. The GlucoLeader Enhance blood glucose meter gave results within 15% of their true blood glucose level 351 out of 360 times. The summary of data for measurements performed by Lot 1 versus YSI 2300 shown below meets the acceptance criteria.

Within±5%	Within±10%	Within±15%	Within±20%
59.7% (215/360)	84.7% (305/360)	97.5% (351/360)	100% (360/360)

### ■ Shelf life evaluation:

- Test strips unopened vial shelf life study: The shelf life of the unopened vial of Test Strips is validated and claimed to be **24 months**.
  - Test strips opened vial stability study: The shelf life of the Test Strips opened vial is claimed to be **90 days**.
  - Control solution unopened vial shelf life stability study: The shelf life of the unopened vial of GlucoLeader Enhance Glucose Control Solutions is validated and claimed to be **18 months**.
  - Control solutions opened vial shelf life stability study: The shelf life of the opened vial of Control Solutions is claimed to be **90 days**.
- Virucidal efficacy against Hepatitis B surface Antigen (HBsAg) by the Clorox Germicidal Wipes disinfectant,
- On main housing materials of ABS (white & blue)
  - On test slot of PMMA (transparent)
  - On LCD display lens of PC (transparent)
  - On Mem and Set buttons of Rubber (black)
  - On label surface layer of PET (transparent)
  - On data port of Polyamide 6T (PA6T) (black)



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- **Conclusions**

The conclusions drawn from the non-clinical & clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.