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

A. 510(k) Number:

k113307

B. Purpose for Submission:

New Device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose dehydrogenase (GDH-FAD)

E. Applicant:

HMD BioMedical Inc.

F. Proprietary and Established Names:

For single patient use:

GoodLife AC-300 Blood Glucose Monitoring System

GoodLife AC-301 Blood Glucose Monitoring System

GoodLife AC-302 Blood Glucose Monitoring System

GoodLife AC-303 Blood Glucose Monitoring System

GoodLife AC-304 Blood Glucose Monitoring System

GoodLife AC-305 Blood Glucose Monitoring System

For multiple patient use:

GoodLife AC-300 Professional Blood Glucose Monitoring System

GoodLife AC-301 Professional Blood Glucose Monitoring System

GoodLife AC-302 Professional Blood Glucose Monitoring System

GoodLife AC-303 Professional Blood Glucose Monitoring System

GoodLife AC-304 Professional Blood Glucose Monitoring System

GoodLife AC-305 Professional Blood Glucose Monitoring System

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LFR – glucose dehydrogenase, glucose	Class II	21 CFR § 862.1345	75-Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR § 862.1345	75-Chemistry
JJX – Single Analyte control	Class I, reserved	21 CFR § 862.1660	75 – Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

GoodLife AC-300 Blood Glucose Monitoring System

The GoodLife AC-300 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 GoodLife AC-300 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-300 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 GoodLife AC-300 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-300 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-300 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-301 Blood Glucose Monitoring System

The GoodLife AC-301 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 GoodLife AC-301 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-301 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 GoodLife AC-301 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-301 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-301 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-302 Blood Glucose Monitoring System

The GoodLife AC-302 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 GoodLife AC-302 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-302 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 GoodLife AC-302 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-302 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh

capillary whole blood samples drawn from the fingertips only.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-302 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-303 Blood Glucose Monitoring System

The GoodLife AC-303 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 GoodLife AC-303 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-303 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 GoodLife AC-303 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-303 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-303 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-304 Blood Glucose Monitoring System

The GoodLife AC-304 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 GoodLife AC-304 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-304 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 GoodLife AC-304 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-304 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-304 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-305 Blood Glucose Monitoring System

The GoodLife AC-305 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 GoodLife AC-305 Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

The GoodLife AC-305 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 GoodLife AC-305 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife AC Blood Glucose Test Strips are for use with the GoodLife AC-305 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-305 Blood Glucose Meter and GoodLife AC Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-300 Professional Blood Glucose Monitoring System

The GoodLife AC-300 Professional 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 fingertips only. The GoodLife AC-300 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-300 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-300 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-300 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-300 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-301 Professional Blood Glucose Monitoring System

The GoodLife AC-301 Professional 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 fingertips only. The GoodLife AC-301 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-301 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-301 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-301 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-301 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-302 Professional Blood Glucose Monitoring System

The GoodLife AC-302 Professional 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 fingertips only. The GoodLife AC-302 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-302 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-302 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the

GoodLife AC-302 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-302 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-303 Professional Blood Glucose Monitoring System

The GoodLife AC-303 Professional 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 fingertips only. The GoodLife AC-303 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-303 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-303 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-303 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-303 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-304 Professional Blood Glucose Monitoring System

The GoodLife AC-304 Professional 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 fingertips only. The GoodLife AC-304 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-304 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-304 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-304 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-304 Professional Blood Glucose Meter and GoodLife AC Professional Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

GoodLife AC-305 Professional Blood Glucose Monitoring System

The GoodLife AC-305 Professional 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 fingertips only. The GoodLife AC-305 Professional Blood Glucose Monitoring System is intended to be used for testing multiple patients by a health care professional in a clinical setting.

The GoodLife AC-305 Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by a health care professional in healthcare facilities as an aid to monitor the effectiveness of diabetes control. The GoodLife AC-305 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife AC Professional Blood Glucose Test Strip are for use with the GoodLife AC-305 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

The GoodLife Glucose Control Solutions are for use with the GoodLife AC-305 Professional Blood Glucose Meter and GoodLife AC Professional 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):
   For over-the-counter and prescription use

   - Not intended for use on neonates
   - Not for 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
   - Single-patient use systems are single-patient use only and should not be shared
   - Multiple-patient use must be disinfected between use following labeling recommendations
   - Multiple patient use systems should only use single use, auto disabling

lancing devices.

4. Special instrument requirements:

   The GL GoodLife AC Series Blood Glucose Meters (Models: AC-300, AC-301, AC-302, AC-303, AC-304, AC-305) for single-patient use and the GL GoodLife AC Series Professional Blood Glucose Meters (Models: AC-300M – AC-301M, AC-302M, AC-303M, AC-304M, AC-305M) for multiple-patient use.

I. Device Description:

The GL GoodLife Blood Glucose Monitoring System Series (Models: AC-300, AC-301, AC-302, AC-303, AC-304, AC-305) and the GL GoodLife Professional Blood Glucose Monitoring System Series (Models: AC-300M, AC-301M, AC-302M, AC-303M, AC-304M, AC-305M) consists of the following components: a glucose meter, glucose test strips and check strips, two (2) levels of glucose control solutions (Level I and Level II), and instructions for use. Each test strip contains 1.5 U of glucose dehydrogenase (FAD) obtained from Aspergillus oryzae, 0.08 mg of potassium ferricyanide, and 0.07 of non-reactive (excipient) ingredients.

1. Predicate device name(s):

   U-RIGHT TD-4279A Blood Glucose Monitoring System

2. Predicate K number(s):

   k101509

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	U-RIGHT TD-4279A Blood Glucose Monitoring System (predicate device), k101509	GL GoodLife and GL GoodLife Professional Blood Glucose Monitoring Systems (candidate devices)
Intended Use/ Indications for Use	It is designed to quantitatively measure the concentration of glucose in fresh capillary whole blood.	Same
Setting	For single and multiple patient use	GL GoodLife for single GL GoodLife Professional for multiple
Detection method	Amperometry	Same

Enzyme	Glucose dehydrogenase-FAD	Same
Calibration Coding	Autocoding	Coding function is combined in each test strip.
Power supply	Two (2) 1.5V AAA size alkaline batteries	One (1) 3V lithium battery
Memory	Meter stores the most recent blood glucose test results	Memory capacity is 999 entries
Test range	20 - 600 mg/dL	20 – 600 mg/dL
Hematocrit range	20 – 70%	30-55%
Sample type	Capillary and venous whole blood	Capillary whole blood
Sample sites	Fingertip	Same
Sample volume	1.1 µL	0.5 µL
Sample test time	7 seconds	5 seconds

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

(1) ISO 15197:2003 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
(2) IEC 60601-1:1988 + A1:1991 + A2:1995 Medical electrical equipment - Part 1: General requirements for safety
(3) lEC 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
(4) CLSI/NCCLS EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods
(5) CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement.
(6) CLSI EP07-A2: Interference Testing in Clinical Chemistry
(7) CLSI/NCCLS EP09-A2: Method Comparison and Bias Estimation Using Patient Samples
(8) FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

L. Test Principle:

The GL GoodLife and GL GoodLife Professional Blood Glucose Monitoring Systems use Glucose dehydrogenase-FAD enzyme chemistry as the standard dry reagent assay for glucose in whole blood. A glucose dehydrogenase sensor based on the carbon electrode adopting the amperometric assay utilizes the enzyme glucose dehydrogenase to catalyze the formation of gluconolactone for the oxidation of glucose. As a result of this reaction, two electrons are produced forming an electrical current that is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

The GoodLife AC-300 Blood Glucose Meter was chosen as the representative meter for the twelve meter models in the single and multiple patient use meter model series. The AC-300 meter was used for all performance studies as the twelve meter models are identical; the only differences between each meter are the shape of the meter and the size and shape of the buttons; however the functions of all twelve meters are identical. The GL GoodLife and GL GoodLife Professional Blood Glucose Monitoring Systems utilizes test strips under two names: GL GoodLife AC Blood Glucose Test Strips (for models: AC-300, AC-301, AC-302, AC-303, AC-304, AC-305) and GL GoodLife AC Professional Blood Glucose Test Strips (for models: AC-300 professional, AC-301 professional, AC-302 professional, AC-303 professional, AC-304 professional, AC- 305 professional glucose meters)

1. Analytical performance:

   a. Precision/Reproducibility:

   Within-run precision was measured by using EDTA venous whole blood as the anti-coagulant at six different glucose concentrations. Each blood sample was adjusted to a hematocrit level ranging from 30-55% and verified by an automated method. Each sample was tested on 3 lots of test strips on 30 meters (10 meters per test strip lot). Ten replicates were tested per meter, test strip lot, and glucose concentration, (N=100 per test strip). Results are summarized below:

Glucose Level (mg/dL)	Strip Lot	YSI (mg/dL)	Mean (mg/dL)	SD (mg/dL)	%CV
30 – 50mg/dL	1	42	45.0	1.8	4.0
	2	42	43.0	1.8	4.2
	3	43	43.0	1.9	4.3
51 - 110 mg/dL	1	104	104.2	3.5	3.4
	2	104	103.9	3.3	3.2
	3	109	103.6	3.4	3.3
111 - 150 mg/dL	1	119	121.8	5.6	4.6
	2	119	123.1	5.2	4.2
	3	122	122.2	5.4	4.5
151 - 250 mg/dL	1	199	193.7	7.1	3.7
	2	199	194.5	7.5	3.9
	3	187	192.2	7.3	3.8
251 - 400 mg/dL	1	297	305.4	8.7	2.8
	2	297	303.8	9.1	3.0
	3	288	301.9	8.1	2.7
401 – 600	1	558	581.3	15.7	2.7

mg/dL	2	558	590.4	16.2	2.7
	3	532	575.1	15.6	2.7

Between-day precision was measured by reading three different control materials on 3 lots of test strips, using 10 test strips on 10 meters (1 strip per meter), over 10 days (N=100 per test strip). Results are summarized below:

Control Level	Strip Lot	YSI (mg/dL)	Mean (mg/dL)	SD (mg/dL)	% CV
Level I	1	44	45.4	2.2	4.8
	2	44	46.5	2.2	4.8
	3	44	45.1	2.1	4.6
Level II	1	108	115.7	4.3	3.7
	2	108	115.0	4.9	4.3
	3	108	114.7	4.8	4.1
Level III	1	302	311.6	10.3	3.3
	2	302	313.3	11.3	3.6
	3	302	311.7	15.1	4.8

b. Linearity/assay reportable range:

The linearity study was designed following CLSI EP6-A guideline. Venous (EDTA) whole blood samples were drawn and spiked to target analyte levels. Eight (8) target levels were prepared with glucose stock solutions to glucose concentrations ranging from <20 mg/dL to >600 mg/dL (18, 40, 107, 119, 184, 276, 476, 615 mg/dL). A total of 480 strips from 3 strip lots were used for this study. Each sample was tested on 160 strips per lot (3 lots of test strips) using two meters. All samples were also tested on a YSI analyzer to generate the expected values. The observed values were plotted against an average of the expected values and an appropriate line fitted by standard linear regression was generated with results summarized below:

Strip Lot	Slope	Intercept	R^2
1	1.01	2.51	0.997
2	0.99	3.23	0.995
3	1.01	0.36	0.997
Combined	1.01	2.03	0.996

The sponsor's claimed measurement range for glucose is 20 -600 mg/dL.

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

Traceability:

The GL GoodLife and GL GoodLife Professional Glucose Monitoring Systems are traceable to the NIST SRM 917a reference material.

Control solutions previously cleared: See k032985 for traceability, stability, and expected value information.

Test Strip Stability:

Shelf Life: GL GoodLife AC blood glucose test strips were stored at (4ºC±2ºC and 45% ±5%RH), (30ºC ±2ºC and 65% ±5%RH), and (42ºC ±2ºC and 75% ±5%RH). For this study, one lot (28 vials, 25 strips per vial) of test strips were used and were divided into 3 groups stored at temp/humidity combinations specified above for real time shelf life stability testing. Glucose values obtained using the GL GoodLife meter were compared to glucose values obtained using YSI reference method at 1, 3, 6, 9, 12,18, and 24 months. The sponsor claims shelf life of 24 months when stored at 50-104 ºF (10-40 ºC). Testing protocols and acceptance criteria were reviewed and found to be acceptable.

Open Vial test strip stability: 156 vials (25 strips per vial) of GL GoodLife AC blood glucose test strips from one (1) lot were divided into 3 groups and stored at (4ºC±2ºC and 45% ±5%RH), (30ºC ±2ºC and 65% ±5%RH), and (42ºC ±2ºC and 75% ±5%RH). Eight (8) different blood glucose concentrations were tested 10 times using one meter. Glucose values obtained using the GL GoodLife meter were compared to glucose values obtained using YSI reference method at 1, 3, 6, 9, 12, and 13 weeks. The sponsor claims open vial stability of 90 days after first opening when stored at 50-104 ºF (10-40 ºC). Testing protocols and acceptance criteria were reviewed and found to be acceptable.

d. *Detection limit:*

See linearity study above.

e. *Analytical specificity:*

Interference study was designed according to CLSI EP7-A2 guideline. Common endogenous and exogenous substances were evaluated for interference by first spiking venous whole blood (collected in tubes containing EDTA) to two levels of glucose concentrations (60-70 mg/dL and 250-350 mg/dL and then dividing each level to a control and test aliquot. The endogenous and exogenous substances to be evaluated were then added to the

test aliquot. Each interfering substance was evaluated at 4 concentrations on 3 lots of test strips. Bias was calculated as the difference between the test and control concentration groups. The following tables show the test concentrations for each potential interfering substance:

Substance	**Therapeutic/ Physiological Levels**	**Highest concentration without interference (mg/dL)**
Acetaminophen[1]	1.00-3.00	20
Ascorbic acid[1]	0.40-2.00	3
Bilirubin[1]	0.29-1.23	40
Cholesterol[1]	150-250	500
Creatinine[1]	0.60-1.30	10
Dopamine[1]	0.03	20
EDTA[1]	N/A	0.1
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
Heparin[1]	350-1000U/L	3000U/L
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	**2000**
Urea[1]	6.60-85.80	600
Uric acid[1]	2.52-8.00	9
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

Reference:
1. The CLSI EP7-A2 Interference Testing in Clinical Chemistry; Approved Guideline- Second Edition
2. k110894 CONTOUR NEXT LINK Wireless BGMS, Bayer Healthcare LLC, Diabetes Care
3. k111890 FORA Diamond Prima & Mini BGMS, Taidoc Technology Corporation
4. k101509 U-RIGHT TD-4279A BGMS, Taidoc Technology Corporation

Lipemic effects: Elevated triglycerides up to 2000 mg/dL do not significantly affect the results

Significant (>+/- 10% bias) interference was noted for xylose at concentrations >50 mg/dL

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System accuracy study:

This study was designed following ISO 15197:2003(E) using 100 fresh capillary blood samples collected from participants from a diabetic clinic and measured using two AC-300 meters. Fingerstick samples were collected by two trained technicians over a 10 day period. Venous blood was also collected and measured on the YSI analyzer. Pooled and altered samples were used for glucose values less than 50mg/dL and greater than 400 mg/dL; each sample allowed to glycolyze or spiked with a stock glucose solution to the desired glucose level. Results obtained using the AC-300 meters were compared to results obtained using the YSI 2300 (reference method). The range of samples tested was 31 – 453 mg/dL. System accuracy results are summarized below:

Lot 1:

System accuracy results for glucose concentration <75 mg/dL with AC-300

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
7/18 (39%)	16/18 (89%)	18/18 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL with AC-300

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
29/82 (35%)	62/82 (76%)	78/82 (95%)	79/82 (96%)

Linear regression between AC-300 and YSI

Accuracy of AC-300 compared to YSI using capillary whole blood	N=100 Y=0.92x+6.54 R^2=0.9752 Sy.x=16.08 Range: 35-453 mg/dL

Lot 2:

System accuracy results for glucose concentration <75 mg/dL with AC-300

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
8/18 (44%)	17/18 (94%)	18/18 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL with AC-300

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
43/82 (52%)	68/82 (83%)	76/82 (93%)	80/82 (98%)

Linear regression between AC-300 and YSI

Accuracy of AC-300 compared to YSI using capillary whole blood	N=100 Y=0.95x+6.51 R^2=0.9815 Sy.x=13.87 Range: 35-453 mg/dL

Lot 3:

System accuracy results for glucose concentration <75 mg/dL with AC-300

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
8/19 (42%)	18/19 (95%)	19/19 (100%)

System accuracy results for glucose concentrations ≥ 75 mg/dL with AC-300

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
43/81 (53%)	70/81 (86%)	78/81 (96%)	79/81 (98%)

Linear regression between AC-300 and YSI

Accuracy of AC-300 compared to YSI using capillary whole blood	N=100 Y=0.92x+6.95 R^2=0.9826 Sy.x=12.59 Range: 31-444 mg/dL

b. Matrix comparison:

None. Only capillary whole blood samples are acceptable matrix.

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 performance study:

This study was conducted following the ISO Standard 15197 and compared layuser self-test fingerstick to the YSI method. This study was performed at three sites (two hospitals and a diabetes clinic) and using capillary blood samples collected by 150 subjects. The glucose sample ranges were from 56 – 388 mg/dL. The results of this study, linearity, and method comparison support the claimed measuring range of 20 - 600 mg/dL.

Regressions between Lay user's fingerstick results and the YSI method/Technician result and the YSI method:

Tester	Linear Regression	R	N
Layperson	Y= 0.99x + 9.35	0.97	150
Technician	Y= 0.95x +3.52	0.99	150

Based on the ISO Standard 15197 document, how well lay-users tested themselves (using fingertip) as compared with the YSI method is shown in the following table:

Glucose concentration < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
3/3(100%)	3/3(100%)	3/3(100%)	
Glucose concentration 75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
56/147(38%)	92/147(63%)	125/147(85%)	141/147(96%)

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:
   For people without diabetes:
   The normal blood glucose range for people without diabetes:

   Fasting and before meals: Less than 100 mg/dL
   2 hours after meals: Less than 140 mg/dL
   American Diabetes Association Position Statement, Diabetes Care Vol.34 (Suppl.1) p.S13 (2011)

N. Instrument Name:

GL GoodLife Blood Glucose Meters (Models: AC-300, AC-301, AC-302, AC-303, AC-304, AC-305) for single patient use and The GL GoodLife Professional Blood Glucose Meters (Models: AC-300M, AC-301M, AC-302M, AC-303M, AC-304M, AC-305M) for multiple patient use.

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and requires a sample volume of 0.5 uL.

   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 _____ 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 _____

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

5. Calibration:

   There is no calibration required for the GL GoodLife meter by the user. The meter is plasma-calibrated.

6. Quality Control:

   GL Glucose control solutions at two different concentrations (Levels 1 and 2) can be run with this device. The meter has an algorithm to automatically recognize the control solutions to prevent control results from being stored in the internal memory as patient result. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results. An acceptable range for each control level is printed on the control solutions vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. Altitude Study:
   This study was conducted at three sites to evaluate the effect of altitude on the GL GoodLife BGMS. One lot of test strips was tested on 4 meters. Eight different venous whole blood (EDTA) glucose concentrations were evaluated on each meter in replicates of five at each site and at altitudes of 0.33 feet, 5,741 feet, and 8,800 feet. The samples tested spanned the device measuring range. These blood samples were evaluated using both the GL GoodLife blood glucose meter and an YSI glucose analyzer. Each test strip glucose value was compared to the YSI method and then analyzed as a percent bias. The glucose values obtained using the GL GoodLife glucose meter had acceptable biases compared to YSI to support use at altitudes up to 8,800 feet. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 8,800 feet have no significant effect on blood glucose measurements from the GL GoodLife and GL GoodLife Professional Blood Glucose Monitoring Systems.

2. Hematocrit Study:
   The sponsor performed hematocrit studies using seven different hematocrit (25, 30, 35, 40, 45, 55, 60%) levels distributed across the glucose measuring range (20 – 600 mg/dL). Each glucose concentration/hematocrit level was tested in replicates of six (6) using one (1) meter. The results support the sponsor's hematocrit claim of 30% - 55%.

3. Temperature and Relative Humidity Study:
   In this study, two meters were evaluated at 10 combined temperature and relative humidity conditions (8ºC, 10ºC, 25ºC, 40ºC, 42ºC with 15% RH and (8ºC, 10ºC, 25ºC, 40ºC, 42ºC with 85%RH). Each sample was compared to the YSI reference method. The meters and test strips were at each temperature/humidity combination for at least 30 minutes prior to glucose concentration testing. Eight venous whole blood samples were adjusted to the following glucose concentration levels: (<20 mg/dL, 20-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL, 401-600 mg/dL, and >600 mg/dL) and were evaluated on each meter in replicates of five (2 meters x 5 replicates). The results demonstrate that accurate readings can obtained after exposure to temperatures ranging from 50 ~ 104ºF (10 ~ 40ºC) and relative humidity conditions at 15 and 85%.

4. EMC Electromagnetic Compatibility and Electrical Safety verification testing of the GL GoodLife Blood Glucose Monitoring System was performed following the requirements of ISO 15197:2003 (E). A signed technical compliance statement was provided demonstrating that EMC testing was performed following standards listed in the test report.

5. Sample volume study:

   HMD Biomedical performed a sample volume study to demonstrate that 0.5µL of whole blood is sufficient volume for the GL GoodLife AC-300 Blood Glucose Monitoring System. For this study, whole blood sample volumes ranging from 0.3µL – 0.7 µL were evaluated using three different lots of test strips. The blood glucose sample results collected using the GL GoodLife Meter were compared with glucose values obtained with the YSI reference method and supported the minimum sample volume claim of 0.5µL.

6. Infection control:

   The device (GL GoodLife and GL GoodLife Professional Blood Glucose Monitoring systems) is intended for single (AC-300 - 305) or multiple patient use (AC-300M - 305M). Clorox Commercial Solutions® Clorox Germicidal Wipes (EPA Reg No.67619-12) were validated by virucide efficacy testing using Hepatitis B surface antigen (HBsAg) using materials from the meter. Robustness studies were also performed demonstrating that there was no change in device performance or in the external materials of the meters after 520

cleaning and disinfection cycles to simulate single-patient use or after 18,250 cleaning and disinfecting cycles to simulate 5 years of multiple patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

7. Readability: A Flesch-Kincaid analysis was conducted and the resulting grade level at which the device labeling is written is as follows:

Labeling	Flesch-Kincaid Grade Level Score
User's Manual	7.9
Test Strip Insert	7.8
Control Solution Insert	7.6

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.