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

A. 510(k) Number:

k161533

B. Purpose for Submission:

New Device

C. Measurand:

Glycosylated Hemoglobin (HbA1c)

D. Type of Test:

Quantitative, boronate affinity chromatography assay

E. Applicant:

BioHermes Co., Ltd.

F. Proprietary and Established Names:

A1C EZ Glycohemoglobin Analysis System

G. Regulatory Information:

Classification Name	Product Code	Device Class	Regulation	Panel
Glycosylated hemoglobin assay	LCP	II	21 CFR 864.7470	81 (Hematology)
Discrete photometric chemistry analyzer for clinical use	JJE	I	21 CFR 862.2160	75 (Chemistry)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use below.

2. Indication(s) for use:

   A1C EZ Glycohemoglobin Analysis System is an in vitro diagnostic test used to quantitatively measure the percent glycohemoglobin A1c or glycohemoglobin A1c fraction mmol/mol in venous whole blood samples. This system is intended for multiple patient use to monitor long term glycemic control in individuals previously diagnosed with diabetes. This test is not to be used for screening or diagnosis of diabetes or for neonatal use. The A1C EZ Glycohemoglobin Analysis System is intended for professional use in clinical laboratories only.

3. Special conditions for use statement(s):

   This test is not for the screening or diagnosis of diabetes or neonatal use

   The analyzer is used for *in vitro* diagnostic use only. Do not use the result of this device to change therapy without guidance from healthcare professionals.

   Use fresh whole blood only. Do not use plasma and serum.

   Patients whose hematocrit (HCT) is too high (> 55%) or too low (< 30%) may not use this product. It may lead to incorrect results.

   This test is for clinical laboratory use only.

   This test is for prescription use only.

   This test should not be used in monitoring daily glucose control and should not replace daily home testing of urine and blood glucose levels.

   This test should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic disease, pregnancy, and significant or chronic blood loss.

4. Special instrument requirements:

   A1C EZ 2.0 Glycohemoglobin analyzer

I. Device Description:

The A1C EZ Glycohemoglobin Analysis System consists of analyzer, test strip(s), buffer A, buffer B, blood sampler (s) and a calibration chip. The analyzer has a voice function.

The A1C EZ Test Strip is composed of an absorbent pad, a plastic film absorbent pad cover, a polyethylene fiber membrane, a plastic film membrane cover and a PET base plate.

Buffer A contains H_2O, sodium chloride, detergent, sodium hydroxide, and Tris-Cl

Buffer B contains H_2O, zinc chloride, detergent, sodium hydroxide, and CAPS.

The sampler consists of handle grip which is made of impact polystyrene and sample loading part which is made of coiled polyester. The sampler is able to absorb the blood sample automatically when the coiled polyester touches the blood drop. The sampler is designed to be able to absorb at least 3µL of blood, which is sufficient for a single test in A1C EZ 2.0 glycohemoglobin analysis system.

Quality Control material is available separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bayer A1CNow+ (Professional Use)

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

   k090413

3. Comparison with predicate:

Similarities/Differences Assay		
Item	Candidate Device A1C EZ Glycohemoglobin Analysis System	Predicate Device A1CNow+ k090413
Intended Use	Quantitative measurement of the percent of glycated hemoglobin (%HbAlc, %A1C) levels in whole blood samples to monitor long term glycemic control in individuals previously diagnosed with diabetes.	Same
Frequency of Use	Repeated Use (analyzer can be used multiple times)	Single use (all materials are disposed at the end of the test)
Sample Type	K2-EDTA, NaF, LiHep venous whole blood	
Calibration	Automatic, not required by end user	Not required by end user; each unit is factory calibrated
Testing Environment	Professional Use	Same
Test Strip Stability	12 months at room	15 months at room

Similarities/Differences Assay		
Item	Candidate Device A1C EZ Glycohemoglobin Analysis System	Predicate Device A1CNow+ k090413
	temperature	temperature
Methodology	Boronate Affinity Lateral Chromatography	Immunoassay
Measuring range	4-14% HbA1c	4-13% HbA1c

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

IEC 62304, Medical device software – software life cycle processes

IEC 61010-1, Safety requirements for electrical equipmenet for measurement, control, and laboratory use – Part 1: General requirements

IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances.

CLSI EP09-A3, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition

CLSI EP05-A2, Evaluation of Precision Perform ance of Quantitative Measurement Methods; Approved Guideline—Second Edition

L. Test Principle:

The A1C EZ Glycohemoglobin Analysis System utilizes the boronate affinity lateral chromatography method to quantitatively measure the percentage of glycohemoglobinA1c (HbA1c) in total hemoglobin. A solid phase separation matrix in the membrane contains both negatively charged groups and boronate groups. When the acidic buffer A flows through the matrix membrane, positively charged hemoglobin (including glycohemoglobin and non-glycohemoglobin) binds to the negatively charged groups. At this time, the device measures the amount of total hemoglobin. When buffer B is added, the pH turns basic and the hemoglobin loses its positive charge. Hemoglobin is released from the matrix, but cis-diols of glycohemoglobin can bind to the boronate groups and stay in the matrix. At this time, the device measures the amount of glycated hemoglobin. The device uses a photometer to measure the reflectance and calculate the ratio of the glycohemoglobin to the total hemoglobin.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Internal Precision Study

An internal precision study was conducted according to CLSI EP05-A2. Two K2-EDTA venous whole blood samples (Level 1 = 5.8%/40 mmol/mol and Level 2 = 12.2%/110 mmol/mol HbA1c) were tested in duplicate for two runs over 20 days on one instrument using three reagent lots (N = 240 total sample measurements). Results for within-run, between-run, between-day, and total precision are as follows:

NGSP units (% HbA1c):

CV %	Lot 1		Lot 2		Lot 3		All lots combined	
	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2
Within-run	3.0%	2.7%	3.4%	2.9%	3.3%	2.9%	3.2%	2.8%
Between-run	0.8%	0.5%	0.0%	0.0%	1.3%	0.0%	0.9%	0.0%
Between-day	2.1%	1.6%	1.1%	0.9%	0.0%	1.0%	0.0%	0.3%
Total	3.8%	3.1%	3.5%	3.0%	3.5%	3.1%	3.3%	2.8%

IFCC units (mmol/mol):

CV %	Lot 1		Lot 2		Lot 3		All lots combined	
	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2
Within-run	4.8%	3.2%	5.4%	3.5%	5.2%	3.6%	5.3%	3.4%
Between-run	1.3%	0.7%	0.0%	0.0%	2.1%	0.0%	1.4%	0.0%
Between-day	3.4%	1.9%	1.7%	1.1%	0.0%	1.2%	0.0%	0.5%
Total	6.0%	3.8%	5.6%	3.6%	5.6%	3.8%	5.8%	4.4%

External Precision Study

An external precision study was conducted at three sites. Two operators per site evaluated three K2-EDTA venous whole blood samples. Samples were tested in two non-consecutive runs for a total of six days with three reagent lots and ten instruments. Results are as follows:

Site-to-site variability:

NGSP units (% HbA1c):

Site	N	5.1% HbA1c		7.3% HbA1c		11.7% HbA1c	
		Mean	%CV	Mean	%CV	Mean	%CV
1	120	5.04	3.0	7.29	2.7	11.49	2.5
2	120	5.16	2.9	7.43	2.5	11.57	2.1
3	120	5.08	2.8	7.40	2.5	11.56	2.2

IFCC units (mmol/mol HbA1c):

Site	N	32 mmol/mol HbA1c		56 mmol/mol HbA1c		104 mmol/mol HbA1c	
		Mean	%CV	Mean	%CV	Mean	%CV
1	120	31.6	5.2	56.2	3.8	102.0	3.0
2	120	32.9	5.0	57.7	3.6	103.0	2.6
3	120	32.0	4.9	57.3	3.5	102.8	2.7

Lot-to-lot variability:

NGSP units (% HbA1c):

Lot	N	5.1% HbA1c		7.3% HbA1c		11.7% HbA1c	
		Mean	%CV	Mean	%CV	Mean	%CV
1	120	5.09	3.2	7.37	2.8	11.57	2.1
2	120	5.10	3.1	7.35	2.6	11.47	2.3
3	120	5.09	3.0	7.41	2.6	11.58	2.4

IFCC units (mmol/mol HbA1c):

Lot	N	32 mmol/mol HbA1c		56 mmol/mol HbA1c		104 mmol/mol HbA1c	
		Mean	%CV	Mean	%CV	Mean	%CV
1	120	32.1	5.5	57.0	4.0	102.9	2.5
2	120	32.2	5.3	56.8	3.7	101.9	2.9
3	120	32.2	5.2	57.5	3.6	103.0	2.9

Operator-to-operator variability:

NGSP units (% HbA1c):

Operator	N	5.1% HbA1c		7.3% HbA1c		11.7% HbA1c	
		Mean	%CV	Mean	%CV	Mean	%CV
1	60	5.04	3.0	7.28	3.0	11.45	2.4
2	60	5.05	3.0	7.30	2.3	11.52	2.5
3	60	5.18	2.8	7.47	2.5	11.56	2.1
4	60	5.15	3.0	7.40	2.5	11.59	2.2
5	60	5.10	3.1	7.44	2.7	11.55	2.2
6	60	5.09	3.0	7.35	2.1	11.57	2.4

IFCC units (mmol/mol HbA1c):

Lot	N	32 mmol/mol HbA1c		56 mmol/mol HbA1c		104 mmol/mol HbA1c	
		Mean	%CV	Mean	%CV	Mean	%CV
1	60	31.5	5.2	56.1	4.2	101.6	3.0
2	60	31.6	5.2	56.2	3.3	102.4	3.1
3	60	33.0	4.9	58.1	3.5	102.8	2.6
4	60	32.8	5.2	57.4	3.6	103.2	2.7
5	60	31.7	4.8	57.8	3.8	102.7	2.5
6	60	32.2	5.0	56.8	3.0	102.9	2.9

Combined to include all sites, operators, instruments, and test strip lots:

NGSP units (% HbA1c)

Sample	N	Total	
		Mean	%CV
5.1% HbA1c	360	5.09	3.1
7.3 % HbA1c	360	7.37	2.7
11.7 HbA1c	360	11.54	2.3

IFCC units (mmol/mol HbA1c)

Sample	N	Total	
		Mean	%CV
32 mmol/mol HbA1c	360	32.2	5.3
56 mmol/mol HbA1c	360	57.1	3.8
104 mmol/mol HbA1c	360	102.6	2.8

b. *Linearity/assay reportable range:*

Linearity was evaluated according to CLSI EP06-A. The linearity of the A1C EZ Glycohemoglobin Analysis System was verified by mixing a high K2-EDTA venous whole blood sample (14.5%) with a low sample (3.6%) to create 11 sample levels covering the assay range (3.6, 4.7, 5.8, 6.9, 8.0, 9.1, 10.1, 11.2, 12.3, 13.4, and 14.5%). All levels were analyzed in singlicate on five instruments with one reagent lot. The mean observed %HbA1c value was determined for each level and plotted versus the % HbA1c value determined by a reference method (Tosoh G8 analyzer).

The linear regression results are as follows:

NGSP units (% HbA1c):

$y = 1.0334x – 0.1628$, $r^2 = 0.9989$

IFCC units (mmol/mol HbA1c):

$y = 1.0377x – 1.4795$, $r^2 = 0.9990$

The study supports the sponsor's claimed measuring range of 4.0-14% HbA1c.

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

Traceability

The A1C EZ Glycohemoglobin Analysis System is certified with the National Glycohemoglobin Standardization Program (NGSP). The NGSP certification expires in one year. See NGSP website for current certification at http://www.ngsp.org.

Stability:

Real time stability studies are ongoing. Accelerated and real time stability protocols and acceptance criteria for the A1C EZ Glycohemoglobin Analysis System were reviewed and considered acceptable to support the sponsor's shelf life claims:

Test kit: 18 months at room temperature
Test strips: 1 month after opening vial (vial is closed after every test) at 39-75°F (4-24°C)

d. *Detection limit:*

Please see linearity study above in M1b.

e. *Analytical specificity:*

An interference study was performed to assess common or known endogenous and exogenous substances that could interfere with the A1C EZ Glycohemoglobin Analysis System. The potential interferents listed below were spiked into two K2-EDTA venous whole blood samples with two different levels of % HbA1c (5.2 and 9.2%). The % HbA1c values of the spiked samples were compared to reference samples (samples containing no interferent). Samples were tested with 10 replicates and non-significant interference was defined as ≤ ± 6% difference relative to the reference sample.

Substance	Highest Concentration tested at which no interference was observed
Acetaminophen	20 mg/dL
Ascorbic Acid	30 mg/dL
Bilirubin, conjugated	600 mg/L
Bilirubin, unconjugated	600 mg/L
Triglycerides	900 mg/dL
Cholesterol	1000 mg/dL
Acetylcysteine	1663 mg/L
Metronidazole	200 mg/L
Ampicillin	1000 mg/L
Acetylsalicylic Acid	1000 mg/L
Doxycycline	50 mg/L
Cyclosporine A	5 mg/L
Theophylline	100 mg/L
Phenylbutazone	400 mg/L
Rifampicin	64 mg/L
Glucose	1000 mg/dL
Glyburide	2 mg/L
Ibuprofen	500 mg/L
Levodopa	20 mg/L
Salicylic acid	599 mg/L
Metformin	40 mg/L
Rheumatoid Factor	491 IU/mL
Hemoglobin	500 mg/dL

Labile A1c interference:

Two K2-EDTA venous whole blood samples (5.0% and 10.5% HbA1c) containing 1200 mg/dL glucose were incubated for three hours at 37°C to facilitate the formation of labile A1c. The samples were tested in replicates of 10 using the A1C EZ Glycohemoglobin Analysis System. The sponsor defined non-significant interference

as ≤ ± 7% difference between samples containing glucose and the control samples. The results support the sponsor's claim that > 5% labile HbA1c does not interfere with the A1C EZ Glycohemoglobin Analysis System.

Carbamylated hemoglobin interference:

Two K2-EDTA venous whole blood samples (5.2% and 7.4% HbA1c) were treated with 4mM potassium cyanate and incubated for two hours at 37°C to facilitate the formation of carbamylated hemoglobin. The samples were tested in replicates of 10 using the A1C EZ Glycohemoglobin Analysis System. The sponsor defined non-significant interference as ≤ ± 7% difference between samples containing potassium cyanate and the control samples. The results support the sponsor's claim that > 5% carbamylated hemoglobin does not interfere with the A1C EZ Glycohemoglobin Analysis System.

Acetylated hemoglobin interference:

Two K2-EDTA venous whole blood samples (5.4% and 9.8% HbA1c) were treated with 20 mM acetylsalicylate and incubated for 16 hours at 37°C to facilitate the formation of acetylated hemoglobin. The samples were tested in replicates of 10 using the A1C EZ Glycohemoglobin Analysis System. The sponsor defined non-significant interference as ≤ ± 7% difference between samples containing acetylsalicylate and the control samples. The results support the sponsor's claim that acetylated hemoglobin does not interfere with the A1C EZ Glycohemoglobin Analysis System.

Total hemoglobin:

The effect of different levels of total hemoglobin was evaluated using K2-EDTA venous whole blood samples (5.7% and 8.7% HbA1c). Erythrocytes and plasma of the same sample were mixed to obtain 10 levels containing total hemoglobin concentrations of 69 – 226 g/L (21.2% - 66.4% hematocrit). The samples were tested in replicates of 10 using the A1C EZ Glycohemoglobin Analysis System. The sponsor defined non-significant interference as < ± 7% difference between samples containing hemoglobin and the known HbA1c concentration. The data supports the claimed total hematocrit range of 30 – 55% g/L.

Hemoglobin variants:

A hemoglobin variant study was performed using 117 K2-EDTA venous whole blood samples (ranging from 3.9 to 10.6% HbA1c) containing known levels of hemoglobin variants C, D, E, S, and F. The samples were tested for % HbA1c in replicates of 10 using the A1C EZ Glycohemoglobin Analysis System and results were compared to results obtained with a reference method (Sebia Capillarys 2 Flex Piercing, k122101). Non-significant interference was defined as ≤ ± 8% difference between the candidate and reference method.

The testing results indicate that there is no significant interference for Hemoglobin C (≤ 44.7%), Hemoglobin D (≤ 41.7%), Hemoglobin E (≤ X32.6%), Hemoglobin S (≤ 37.8%), and Hemoglobin F (≤ 14.7%).

The labeling contains the following statement: "The results from the A1C EZ 2.0 Glycohemoglobin Analysis System show that there is no significant interference for Hemoglobin C (≤ 44.7%), Hemoglobin D (≤ 41.7%), Hemoglobin E (≤ X32.6%), Hemoglobin S (≤ 37.8%) and Hemoglobin F (≤ 14.7%)."

Hemolysis

The effect of hemolysis was evaluated using three K2-EDTA venous whole blood samples (5.7%, 7.9% and 9.9% HbA1c) containing up to 7700 mg/dL hemolysate generated from the same samples. Samples were each tested with 10 A1C EZ 2.0 Glycohemoglobin Analysis instruments and one test strip lot, and results were compared to results from control samples without added hemolysate. The sponsor defined non-significant interference as ≤ ± 6% difference between hemolyzed samples and control samples. The results support the sponsor's claim that hemolysis of up to 5000 mg/dL has no significant effect on HbA1c measurements obtained with the A1C EZ Glycohemoglobin Analysis System.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Internal Method Comparison Study

An internal method comparison study was conducted according to CLSI EP09-A2. Up to 120 K2-EDTA venous whole blood samples ranging from 4.2% to 13.3% HbA1c were analyzed in singlicate with three reagent lots over five days on the A1C EZ Glycohemoglobin Analysis System and compared to measurements obtained for the same samples on the Tosoh G8 HPLC analyzer and the A1cNow+ device. The linear regression results are as follows:

NGSP units (% HbA1c):

Comparative Method	N	% HbA1c	Lot	Slope	Intercept	R^2
Tosoh G8	120	4.2 to 13.3	1	0.971	0.201	0.993
			2	0.977	0.176	0.992
			3	0.987	0.124	0.993
A1cNow+	118	4.1 to 12.7	1	0.966	0.203	0.963
			2	0.976	0.152	0.967
			3	0.989	0.079	0.971

IFCC units (mmol/mol HbA1c):

Comparative Method	N	% HbA1c	Lot	Slope	Intercept	R^2
Tosoh G8	120	23.5 to 121.9	1	0.975	1.326	0.985
			2	0.979	1.266	0.984
			3	0.989	0.957	0.985
A1cNow+	118	21.3 to 115.3	1	0.966	1.431	0.963
			2	0.975	1.127	0.967
			3	0.988	0.652	0.971

b. Matrix comparison:

46 matched K2-EDTA, lithium heparin, and sodium fluoride venous whole blood samples ranging from 4.4 to 13.4% HbA1c were tested in singlicate with one reagent lot on the A1C EZ Glycohemoglobin Analysis System. Results were compared to measurements obtained for the same samples with the Tosoh HLC-723 G8 (k131580). Linear regression analysis:

NGSP units (% HbA1c) :

	K2-EDTA	Lithium Heparin	Sodium Fluoride
Slope	1.0048	0.9786	0.9976
Intercept	0.0074	0.1037	-0.0430
R^2	0.9940	0.9942	0.9947

IFCC units (mmol/mol HbA1c) :

	K2-EDTA	Lithium Heparin	Sodium Fluoride
Slope	1.0036	0.9790	0.9986
Intercept	0.3156	0.6082	-0.5984
R^2	0.9878	0.9886	0.9886

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):

   Not applicable.

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

   The sponsor provides the following in the labeling: The American Diabetes Association (ADA) recommendations are summarized in the following table:

% HbA1c (mmol/mol)	Glycemic Control
<8% (64 mmol/mol)	Less stringent
< 7% (53 mmol/mol)	General (non-pregnant adult)
< 6% (48 mmol/mol)	More stringent

   HbA1c values above 6.5% HbA1c (48mmol/mol) are an indication of hyperglycemia during the preceding 2 to 3 months or longer.

   Source:

   American Diabetes Association. Position Statement: Standards of medical care in diabetes - 2012. Diabetes Care 2012;35 (Suppl 1):S11–S63.

N. Instrument Name:

A1C EZ Glycohemoglobin analyzer

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes _____ 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 _____

3. Specimen Identification:

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

4. Specimen Sampling and Handling:

   The user collects venous blood samples by pipetting 4-5µL of whole blood onto the blood sampling device that is supplied as part of the kit.

5. Calibration:

   Calibration is automatic and obtained by inserting a calibration code chip into the device. Each kit contains a lot-specific calibration code chip. The calibration is traceable to the International Federation of Clinical Chemistry (IFCC) and the device is certified with the NGSP standardization program.

6. Quality Control:

   Low and high levels of quality control material intended for use with the A1c EZ 2.0 Glycohemoglobin Test System are available for purchase.

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

Vibration Study

In order to validate the effect of vibration of device during the test, the devices were put on the surface of a shaker during testing. The shaker rotated in a manner where the buffer used in the test would not be shaken out of the device (~15rpm). Three K2-EDTA venous whole blood samples (5.0%, 6.4% and 10.3% HbA1c) were tested with ten devices in replicates of 20 for each sample (two measurements for each sample per device). The average value,

coefficient of variation, and % bias were calculated and compared with the results obtained from tests under normal conditions. The results support the sponsor's claim that vibration during testing does not affect test results.

Sample Volume Study

The blood sampling device is designed to absorb 2.5-4.5 µL of capillary fingerstick or venous whole blood. The sponsor provided a study to show that the total volume of blood absorbed by the blood sampling device ranges from 2.9 to 4.0µL with a mean volume of 3.5µL. The sponsor then investigated the effect of low or high sample volume on the test. 0.5µL, 1.5 µL, 3µL, 4µL, or 5.5 µL of K2-EDTA venous whole blood (5.9%, 8.4% and 10.4% HbA1c) was pipetted onto the coiled polyester of the blood sampler. Each sample was tested once on a total of ten devices. The bias and % bias compared to the known HbA1c concentration in the samples were calculated. For 0.5µL, the device reported error code E7 for all data points. The results support the sponsor's claim that low or high blood volume does not affect the test results.

Operating Conditions Study

In order to verify the effectiveness of the A1C EZ Glycohemoglobin Analysis System at extreme operating conditions, the sponsor tested three K2-EDTA venous whole blood samples (5.2%, 7.4%, and 10.2% HbA1c) on 10 EZ 2.0 instruments at the following operating condition combinations: 11℃/11% RH, 10℃/90%RH, 38℃/10%RH, and 40℃/90%RH. Results were compared to %HbA1c observed for the same samples at 22℃/40%RH and %bias was calculated. The results support the sponsor's claim for operation of the device at temperatures of 50 to 104°F (10 to 40°C) and 30 to 75% relative humidity.

Infection Control Studies

Disinfection efficacy studies were performed on the materials comprising the meter to demonstrate complete inactivation of Hepatitis B virus with Clorox Healthcare Bleach Germicidal Wipes (EPA #67619-12). Robustness studies were performed to demonstrate that there was no change in performance or in external materials of the meter after 18250 disinfection cycles with Clorox Healthcare Bleach Germicidal Wipes. The robustness studies were designed to simulate 5 years of multiple-patient use with 10 disinfections per day.

Readability assessment

A Flesch-Kinkaid reading level assessment was conducted demonstrating that the user manuals and test strip package inserts were written at an 7th grade reading level.

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.