510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM

A. 510(k) Number:

K181751

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Hemoglobin

D. Type of Test:

Quantitative determination of hemoglobin

E. Applicant:

HemoCue AB

F. Proprietary and Established Names:

HemoCue Hb 801 System

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.5620, Automated hemoglobin system

2. Classification:

   Class II

3. Product code:

   GKR, System, hemoglobin, automated

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   The HemoCue Hb 801 System is intended for the quantitative determination of hemoglobin in capillary or venous whole blood (K_2EDTA and Li-Heparin) in point-of-care settings. The HemoCue Hb 801 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old. The HemoCue Hb 801 System is for professional *in vitro* diagnostic use only.

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   HemoCue Hb 801 Analyzer

I. Device Description:

The HemoCue Hb 801 System consists of the following parts: HemoCue Hb 801 Analyzer and HemoCue Hb 801 Microcuvettes. The HemoCue Hb 801 Microcuvettes are single-use cuvettes made of polystyrene plastic which do not contain reagents or active ingredients. The HemoCue Hb 801 Analyzer contains a microcuvette holder. The microcuvette serves both as a pipette and as a measuring cuvette. A whole blood sample of approximately 10 µL is drawn into the cavity of the microcuvette by capillary action. The HemoCue Hb 801 Analyzer provides a direct reading of the hemoglobin concentration on a display screen and has the ability to transmit results by wired connection with the USB cable connected to the power adapter or wirelessly by Bluetooth connection.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   HemoCue Hb 301 System

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

   K061047

3. Comparison with predicate:

Similarities		
Item	Candidate HemoCue Hb 801 System	Predicate HemoCue Hb 301 System K061047
Intended Use	The HemoCue Hb 801 System is intended for the quantitative determination of hemoglobin in capillary or venous whole blood (K_2EDTA and Li-Heparin) in point-of-care settings. The HemoCue Hb 801 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old. The HemoCue Hb 801 System is for professional *in vitro* diagnostic use only.	The HemoCue Hb 301 System is designed for quantitative point-of-care whole blood hemoglobin determination in primary care using a specially designed analyzer, the HemoCue Hb 301 Analyzer, and specially designed microcuvettes, the HemoCue Hb 301 Microcuvettes. The HemoCue Hb 301 System is for In Vitro Diagnostic use only. The HemoCue Hb 301 Analyzer is only to be used with HemoCue Hb 301 Microcuvettes.
Analyte	Hemoglobin	Same
Sample preparation (pre-treatment)	None	Same
Sample volume	10 µL	Same
Measurement principle	Spectrophotometric	Same
Reagent	No active ingredients in microcuvettes	Same
Result	Quantitative	Same
Calibration	The system is traceable to the hemiglobincyanide (HiCN) method, according to ICSH (International Council for Standardization in Haematology). The system is factory calibrated and needs no further calibration.	Same
Quality control	Internal self-test (verifying analyzer performance) External quality control HemoTrol WB	Same
Operating temperature	10–40ºC (50–104°F)	Same
Microcuvette Storage	10–40°C (50–104°F)	Same

Differences		
Item	Device HemoCue Hb 801 System	Predicate HemoCue Hb 301 System K061047
Sample type	Capillary or venous whole blood	Capillary, venous or arterial whole blood
Measuring range	1–25.6g/dL	0–25.6 g/dL
Connectivity	• Wireless Bluetooth Low Energy (Bluetooth Low Energy) • USB	Serial port
Microcuvette insertion technique	Slot in	Place on a tray
Dimensions	87×143×45 mm (3.4×5.6×1.8 inch)	160×140×70 mm (6.3×5.5×2.8 inch)
Power sources	• USB adapter • 3 × AA battery • Rechargeable Li-Ion Battery	• AC adapter • 4 × AA battery
User interface	• Display • Beeper • Two buttons • Status LED	• Display • Beeper • One button
Result memory	Up to 4000 results	No
Clock (Date/time)	Yes	No

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

CLSI EP05-A3; Evaluation of Precision Performance of Qualitative Measurement Methods; Approved Guideline - Third Edition.

CLSI EP06-A; Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

CLSI EP07-A2; Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition.

CLSI EP07; Interference Testing in Clinical Chemistry; Approved Guideline -Third Edition

CLSI EP17-A2; Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition.

CLSI EP25-A; Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.

CLSI EP28-A3c; Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition.

CLSI EP37; Supplemental Tables for Interference Testing in Clinical Chemistry - First Edition

CLSI H15-A3; Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition.

IEC 61010-1: 2010 (Third Edition) + AMD1:2016, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements.

IEC 61010-2-101:2015 (Second Edition), Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

IEC 61326-1:2012 (Second Edition), Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.

IEC 61326-2- 6:2012, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

IEC 62304:2006, Medical device software - Software life cycle processes

ISO 14971:2007, Medical devices - Application of risk management to medical devices

L. Test Principle:

According to the instructions for use, whole blood capillary samples are collected from the puncture of the fingertip using high-flow lancets (not included with the HemoCue Hb 801 System), and filled directly into the microcuvette which is inserted into the HemoCue Hb Analyzer. The analyzer measures the whole blood at an Hb/HbO2 isosbestic point (506 nm) and at a wavelength (880 nm) to compensate for possible interfering background (e.g. turbidity). The measurement is performed directly on the whole blood through measurement of the transmitted and scattered light using an algorithm for translation into the hemoglobin concentration of the sample. The HemoCue Hb 801 System is traceable to the HiCN method, the international reference method according to International Council for Standardization in Hematology (ICSH) for the determination of the hemoglobin concentration in blood. The system is factory calibrated and needs no further calibration by the operator.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Precision - Whole Blood

      Venous K_2EDTA whole blood samples were collected from six healthy subjects and processed to six hemoglobin (Hb) concentrations.

      Multi-microcuvette lots

The six samples were analyzed at a single site over five days, with five runs, five replicates per run per day, and three microcuvette lots, providing 75 measurements for each Hb level. The HemoCue Hb 801 System demonstrates acceptable reproducibility across multiple lots of microcuvettes.

Hb-levels (g/dL)	Replicates	Repeatability		Within-Lab Precision		Reproducibility	
		SD (g/dL)	%CV	SD (g/dL)	%CV	SD (g/dL)	%CV
2.0–3.0	75	0.05	-	0.05	-	0.05	-
6.0–7.0	75	0.07	-	0.08	-	0.08	-
9.5–10.5	75	-	0.68	-	0.71	-	1.11
13.5–14.5	75	-	0.71	-	0.82	-	1.16
16.5–17.0	75	-	0.60	-	0.73	-	0.95
23.0–24.0	75	-	0.67	-	0.77	-	0.97

Multi-site study

Six venous K_2EDTA whole blood samples were analyzed at three sites (one instrument per site) over five days, with five runs, five replicates per run, and one microcuvette lot, providing 75 measurements for each Hb level. The HemoCue Hb 801 System demonstrates acceptable reproducibility across multiple sites.

Hb-levels (g/dL)	Replicates	Repeatability		Within-Lab Precision		Between-Site Precision		Reproducibility	
		SD (g/dL)	%CV	SD (g/dL)	%CV	SD (g/dL)	%CV	SD (g/dL)	%CV
2.0–3.0	75	0.03	-	0.04	-	0.01	-	0.05	-
6.0–7.0	75	0.07	-	0.07	-	0.03	-	0.08	-
9.5–10.5	75	-	1.04	-	1.17	-	1.13	-	1.63
13.5–14.5	75	-	0.71	-	0.75	-	0.66	-	1.00
16.5–17.0	75	-	0.52	-	0.63	-	0.21	-	0.66
23.0–24.0	75	-	0.74	-	0.74	-	0.49	-	0.89

Precision - Quality Control Material

External hemoglobin control material (HemoTrol WB, manufactured by EuroTrol) at three different Hb-levels, was tested at three sites (one analyzer per site), three microcuvette lots (one lot per site), by ten operators (minimum 2 operators per site), over 20 operating days. The samples were tested with two runs per day and two replicates per run, providing 80 measurements for each level. The HemoCue Hb 801 System demonstrates acceptable reproducibility and between-operator precision.

Control Level	N	Mean value (g/dL)	Repeatability		Within-Site Precision		Reproducibility	
			SD (g/dL)	%CV	SD (g/dL)	%CV	SD (g/dL)	%CV
Low	240	6.34	0.05	0.70	0.04	0.70	0.06	0.90
Medium	240	11.50	0.05	0.40	0.05	0.50	0.06	0.50
High	240	15.36	0.15	1.00	0.16	1.00	0.17	1.10

Control Level	Between-operator Precision											
	All Operators				Operators in CLIA-waived setting				POC Operators			
	N	Mean (g/dL)	SD (g/dL)	% CV	N	Mean (g/dL)	SD (g/dL)	% CV	N	Mean (g/dL)	SD (g/dL)	% CV
Low	240	6.34	0.03	-	80	6.31	0.00	-	80	6.35	0.00	-
Medium	240	11.50	-	0.04	80	11.48	-	0.00	80	11.49	-	0.06
High	240	15.36	-	0.00	80	15.34	-	0.01	80	15.32	-	0.02

Precision – K_2EDTA Whole Blood

Fourteen native venous K_2EDTA whole blood samples, Hb-level ranged 7.5–16.8 g/dL, were analyzed at one site over four days, with three instruments, one microcuvette lot, and ten replicates, providing 420 measurements. The HemoCue Hb 801 System demonstrates acceptable reproducibility with native venous K_2EDTA whole blood samples.

Hb-Level group	Sample Number	Replicate Number	Repeatability %CV
Medical Decision level (MDL) (~ 7 g/dL)	2	60	1.02
Normal Hb-level (12–18 g/dL)	12	360	0.97

Precision-Capillary Blood

Forty-two capillary whole samples were analyzed at one site over four days, with one instrument, one microcuvette lot, and ten replicates, providing 420 measurements. The samples ranged 1.5–23.5 g/dL Hb concentration and included four K_2EDTA contrived samples to cover the MDL at 7 g/dL and the low and high ends of analytical measuring range (AMR). The HemoCue Hb 801 System demonstrates acceptable reproducibility with capillary blood samples.

Hb-Level (g/dL)	Sample Number	Sample range (g/dL)	SD (g/dL)	%CV
≤ 7.0	2	1.4–5.0	0.11	-
>7.0	40	7.1–23.3	-	2.30

b. *Linearity/assay reportable range:*

One venous K_2EDTA blood sample was diluted to nine different Hb-levels (0.5, 3.78, 7.05, 10.33, 16.60, 16.88, 20.15, 23.43, and 26.7 g/dL) to span the claimed AMR of the HemoCue Hb 801 System (1.0–25.6 g/dL). Each Hb-level was analyzed with three analyzers and five replicates per analyzer. The HemoCue Hb 801 System demonstrates linearity over the claimed AMR of 1.0–25.6 g/dL.

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

Microcuvette Shelf-Life

HemoCue Hb 801 Microcuvette shelf-life was determined by using three lots of microcuvettes with one lot kept open to study in-use stability over nine months (Time 0, 7 weeks, 3 months ± 2 weeks, 6 months ± 2 weeks, and 9 months). Measurements taken at these time points were compared with the hemiglobincyanide (HiCN) method. HiCN method is the ICSH reference method and was manually performed per ICSH recommendations. The absorbance was detected by a spectrometer. The data support a shelf-life stability claim of 6 months.

Microcuvette Transportation

HemoCue Hb 801 Microcuvette stability during transportation was determined by using one lot of microcuvette over six months (Time 0, 2 weeks, 3 months ± 2 weeks, and 6 months ± 2 weeks). To mimic the transportation conditions, microcuvettes were cycled between two temperatures (-20±2°C and 52±2°C) and afterwards stored at one of the following storage temperatures, 5±3°C or 42±2°C. Measurements taken at these timepoints were compared with the HiCN method. The data support a transportation stability claim of 6 months.

d. Detection limit:

LoB

To determine Limit of Blank (LoB), plasma samples were obtained from four venous K_2EDTA whole blood samples. The study was conducted with three analyzers, two microcuvette lots, and over four operating days. Each sample was analyzed in three runs per day and two replicates per run, providing a total of 144 replicates. LoB was calculated by rank ordering the 72 samples per microcuvette lot from low to high and averaging the 68th and 69th results (being the 95th percentile). LoB was determined to be 0.26 g/dL.

LoD

To determine Limit of Detection (LoD), four venous K_2EDTA whole blood samples were collected covering a Hb concentration range of 0.46–1.0 g/dL. The study was conducted with three analyzers, two microcuvette lots, and over four operating days. Each sample was analyzed three runs per day and two replicates per run, providing 72 replicates per microcuvette lot. LoD was calculated by nonparametric analysis and was determined to be 0.3 g/dL.

LoQ

To determine Limit of Quantitation (LoQ), four venous K_2EDTA blood samples were collected covering Hb concentration 0.37–0.52 g/dL. The study was conducted with three analyzers, two microcuvette lots, and over four operating days. Each sample was analyzed three runs per day and three replicates per run, providing 108 replicates

per microcuvette lot. LoQ was determined from the specified total error to be 0.5 g/dL.

e. *Analytical specificity:*

Venous K_2EDTA whole blood samples were adjusted to two Hb levels (10.0±0.5 g/dL and 20.0±1.0 g/dL). The samples were divided into two groups: a test group and a reference group that serves as the control. The test group was spiked with the interfering substance in NaCl solution as the diluent solution; the reference group was added with a corresponding volume of diluent solution. Each condition (one hemoglobin level with one interfering substance or control) was analyzed with three blood samples, three analyzers, and five replicates per analyzer, providing a total of 45 replicates. A high concentration per CLSI EP07-A2 recommendation of each substance was tested. The results from the test groups were compared with the reference group and if the difference was within ±10%, no interference was determined to be the outcome. For substances identified as interferents at the high concentration tested, a concentration-response curve evaluating multiple concentrations of the interfering substance was generated to determine the non-interfering concentration.

To evaluate the impact on hemoglobin measurements by disease conditions, venous K_2EDTA blood specimens from 5–42 donors of each the following conditions were collected and tested: high white blood cell (WBC) count, sickle cell, polycythemia vera, thalassemia/hypochromia, microcytic hypochromic anemia, normocytic normochromic anemia, macrocytic anemia, autoimmune hemolytic anemia (spherocytosis), dual RBC populations (post-transfusion samples), NRBC, polychromasia, hemoglobin C disease, blood borne parasite (malaria), rouleaux, and agglutination. The Hb concentration from HemoCue Hb 801 System was compared to the HiCN method. Each sample was tested in three or five replicates on HemoCue Hb 801 System and 2–3 replicates with HiCN method. The following conditions, within the acceptance criteria demonstrated no interference effect on the HemoCue Hb 801 System: sickle cell, polycythemia vera, thalassemia/hypochromia, microcytic hypochromic anemia, normocytic normochromic anemia, macrocytic anemia, autoimmune hemolytic anemia (spherocytosis), dual RBC populations (post-transfusion samples), NRBC, polychromasia, hemoglobin C disease, blood borne parasite (malaria), rouleaux, and agglutination.

Substances showed no significant interference up to the concentrations listed below:

Potential interferent	Test concentration	Unit	Potential interferent	Test concentration	Unit
Acetaminophen	1324	µmol/L	**Intralipid**	214	mg/dL
Creatinine	442	µmol/L	**Conjugated bilirubin**	23	mg/dL
Ibuprofen	2425	µmol/L	**Unconjugated bilirubin**	12	mg/dL
Simvastatin	49	µmol/L	**Hemolysis**	1	g/dL

Potential interferent	Test concentration	Unit	Potential interferent	Test concentration	Unit
Tetracycline	34	µmol/L	**HbCO**	10	%
Warfarin	32.5	µmol/L	**HbO2 Low**	50	%
Ascorbic acid	342	µmol/L	**MetHb**	25	%
Salicylic acid	4.34	mmol/L	**pH**	8	N/A
Urea	42.9	mmol/L	**Li-Heparin**	5 × normal concentration (85 IU/mL blood)	
Uric acid	1.4	mmol/L	**K_2EDTA**	5 × normal concentration (9 mg/mL blood)	
Protein	15	mg/dL	**Platelets**	2000×10^9	cells/L
Triglycerides	1500	mg/dL	**WBC**	260×10^9	cells/L

The following substances were found to interfere at the indicated concentrations:

Substance	Substance Concentration	Hemoglobin Concentration Tested	Results
Conjugated bilirubin	> 23 mg/dL	10	Interfering
	≤ 40 mg/dL	20	Non-interfering
Unconjugated bilirubin	> 12 mg/dL	10	Interfering
	> 23 mg/dL	20	Interfering
Intralipid	> 214 mg/dL	10	Interfering
	> 483 mg/dL	20	Interfering
Leukocytes	$> 260 \times 10^9$ /L	6.8–14.7	Interfering

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were performed across five point-of-care (POC) sites to compare the HemoCue Hb 801 System to the predicate device, the HemoCue Hb 301 System. A total of 233 capillary samples and 264 venous K_2EDTA whole blood specimens from a total of 285 subjects were tested at five U.S. sites of primary care setting with both the Hemocue Hb 801 System and the predicate. All samples were measured in duplicate and only the first replicate for each sample was used for the data analysis.

A total of 135 male and 150 female subjects, ranging from 29 days to 95 years of age, provided 233 capillary samples ranging from 4.7–23.2 g/dL and 264 venous K_2EDTA samples ranging from 1.5–25.3 g/dL when tested on the HemoCue Hb 801 System. Of the 497 samples, 28 (6%) contrived venous K_2EDTA samples were collected at one site and tested to challenge the full measuring range of the HemoCue Hb 801 System. In addition, the samples tested for the method comparison study included

samples from patients with anemia and thalassemia as well as samples around the lower medical decision levels.

Testing was performed by 13 operators (2–3 per site) using six analyzers (1–2 per site) and three lots of HemoCue Hb 801 microcuvettes. Linear regression analyses demonstrate comparable performance between the HemoCue Hb 801 System across the AMR.

Blood Type	Sample Number	Slope (95% CI)	Intercept (95% CI)	r
Venous	264	1.00 (0.99, 1.01)	-0.14 (-0.26, -0.33)	1.00
Capillary	233	1.07 (1.02 to 1.12)	-0.91 (-1.54 to -0.28)	0.96
Combined	497	1.01 (1.00, 1.02)	-0.19 (-0.33, -0.06)	0.99

Predicted bias at MDL 7 g/dL along with 95% CIs:

Blood Type	Mean Bias at MDL 7 g/dL (95% CI) (g/dL)
Venous	-0.1 (-0.2, -0.1)
Capillary	-0.4 (-0.7, -0.1)
Combined	-0.1 (-0.2, -0.1)

b. Matrix comparison:

A comparison between K_2EDTA and Li-heparin venous blood was performed on HemoCue Hb 801 System. Paired natural K_2EDTA and Li-heparin samples (n=131), ranging from 2.4–23.6 (K_2EDTA) or 2.5–23.4 (Li-heparin) g/dL Hb, demonstrated comparable performance. In addition, a comparison between capillary and venous K_2EDTA blood was performed on the HemoCue Hb 801 System. Paired capillary and venous K_2EDTA samples without anticoagulant (n=212), ranging from 4.7–23.2 (capillary) or 4.8–23.4 (K_2EDTA) g/dL Hb, demonstrated comparable performance.

Comparison	Sample Number	Slope (95% CI)	Intercept (95% CI)	r
K_2EDTA vs Li-Heparin venous whole blood	131	0.99 (0.99, 1.00)	0.12 (0.06, 0.17)	1.00
Venous vs Capillary	252	1.01 (0.98, 1.03)	-0.05 (-0.33, 0.23)	0.95

Predicted bias at MDL 7 g/dL along with 95% CIs:

Comparison	Mean Bias at MDL 7 g/dL (95% CI)
K2EDTA vs Li-Heparin venous whole blood	-0.2% (-2.3%, 1.9%)
Venous vs Capillary	1.1% (0.6%, 1.5%)

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:

Reference ranges were verified by testing whole blood specimens from healthy donors using the HemoCue Hb 801 System. The reference ranges were based on the existing medically accepted published reference ranges[1,2].

Population	Age Range	Sample Number Tested	Cited Reference Range (g/dL)
Adult Male	≥ 22 years	45	13.0–17.0 [1]
Adult Female	≥ 22 years	43	12.0–15.0 [1]
Adolescent	12 years to < 18 years old	20	10.9–15.1 [2]
Child	> 2 years to 12 years	24	11.0–15.5 [1]
Infant	1 month to 2 years	28	9.4–14.1 [1]

[1] Dacie and Lewis Practical Haematology, Elsevier Limited, 11th Edition, 2011 and references herein
[2] Soldin, S. J. Pediatric Reference Intervals, AACC Press; 7th edition, 2011

N. Instrument Name:

HemoCue Hb 801 System

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 ___X_____ or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes ___X_____ or No _____

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 for the HemoCue Hb 801 system.

4. Specimen Sampling and Handling:

   The Hemocue 801 microcuvette draws a small amount (approximately 10µL) of venous or capillary blood by capillary effect. The cuvette is then inserted into the meter. No reagent is required.

5. Calibration:

   The HemoCue Hb 801 Analyzer is factory calibrated and needs no further calibration.

6. Quality Control:

   The HemoCue Hb 801 System is intended to be used with the HemoTrol WB control materials, manufactured by EuroTrol, in three concentrations that correspond to three levels of human hemoglobin (~ 95, 130, and 160 g/L). Each vial contains 1 mL of HemoTrol WB solution that contains purified bovine hemolysate, stabilizer, and preservatives. Users are directed to perform control testing when an external quality control is required by local or other regulations. The EuroTrol HemoTrol WB is concurrently cleared under K182744.

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

a. Operating Environment

   The operation of HemoCue Hb 801 was tested under the following three conditions: 8–10°C and ≤ 30% relative humidity (RH); 24–26°C and ≥ 90% RH; 40–42°C and 75–80% RH. Three contrived venous K_2EDTA samples at hemoglobin levels 5.0±0.5, 14.0±0.5, and 20.0±1.0 g/dL were tested over three operating days. Acceptable results were achieved under all conditions tested.

b. Cleaning and Disinfection Validation Study

A cleaning and disinfection validation study was conducted to validate virucidal efficacy using the selected disinfectant with the recommended disinfection protocol. Super Sani-Cloth Germicidal Disposable Wipes (EPA Registration No. 9480-4), a ready to use pre-saturated towelette, demonstrated complete inactivation of Duck Hepatitis B virus (surrogate for Human Hepatitis B virus) for all tested materials, following 2-minute wet-contact time. Results of the study also demonstrate no significant change in appearance and function of the HemoCue Hb 801 System after 3000 disinfection and cleaning cycles.

c. Accuracy

An accuracy study was performed by testing 102 venous K_2EDTA whole blood samples (45% contrived) and 100 capillary blood samples on the HemoCue Hb 801 System and using HiCN method. Samples were tested on one analyzer Hemocue Hb 801 System, three lots of microcuvette, over ten days. The regression analysis of venous or capillary samples suggested an agreement between HemoCue Hb 801 System and HiCN method (ICSH reference method).

Blood Type	Sample Number	Slope	Intercept	r
Venous	102	0.99	0.087	1.00
Capillary	100	0.96	0.92	0.92

d. Sample Stability

Sample stability was assessed using five venous K_2EDTA whole blood samples at either room temperature (23±2˚C) or refrigerated temperature (5±3˚C). All samples were analyzed with one lot of microcuvette, three analyzers, and four replicates over 25 hours (0, 4, 8, 20, and 25 hours). The study data supported the recommended stability claim of 24 hours when stored at room temperature (23±2˚C) or refrigerated temperature (5±3˚C).

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.