February 1, 2019

HemoCue AB
Maria Fagerberg
Director Regulatory Affairs
Kuvettgatan 1
Angelholm, Sweden SE-26271

Re: K181751
Trade/Device Name: HemoCue Hb 801 System
Regulation Number: 21 CFR 864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: Class II
Product Code: GKR
Dated: June 27, 2018
Received: July 2, 2018

Dear Maria Fagerberg:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181751

Device Name
HemoCue® Hb 801 System

Indications for Use *(Describe)*

The HemoCue® Hb 801 System is intended for the quantitative determination of hemoglobin in capillary or venous whole blood (K2EDTA 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.

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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Enclosure 1

510(k) Summary

1. Submitter and contact information

Submitter:

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Date of preparation:

Date:	June 27, 2018

2. Device information

Proprietary name**:**	HemoCue® Hb 801 System
Common name:	Hemoglobin analyzing system
Regulation:	Automated hemoglobin system (21 CFR § 864.5620)
Product code:	GKR
Classification:	Class II
Common name:	Hemoglobin analyzing system
Panel:	Hematology

3. Device description

The HemoCue® Hb 801 System provides a direct reading of the hemoglobin concentration in a sample using specially designed, single use microcuvette and an analyzer.
The system can be used by non-laboratory personnel.

The HemoCue® Hb 801 System consists of the following parts:

- An analyzer supporting the following features:
  - Photometric determination of hemoglobin
  - Presentation of results on a display
  - Wired and wireless communication (USB and Bluetooth)
- Power supply by power adapter, chargeable or non- chargeable batteries
- Single use microcuvettes (test consumable)
- Labeling:
  - Operating Manual
  - Package Insert
  - Quick reference Guide
  - Labels

The microcuvette serves both as a pipette and as a measuring cuvette. No dilution or other preparation of the blood sample is required before filling of the microcuvette. A whole blood sample of approximately 10 µL is drawn into the cavity in the microcuvette by capillary action.

The measurement takes place in the analyzer, which measures the absorbance of whole blood at an Hb/ HbO_2 isosbestic point. The measurement is performed directly on the whole blood through measurement of the transmitted and scattered light and using an algorithm for translation into the hemoglobin concentration of the sample.

The HemoCue® Hb 801 System is traceable to the hemiglobincyanide (HiCN) method, the international reference method according to ICSH for the determination of the hemoglobin concentration in blood.

4. Intended use and Indications for Use

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.

Indications for Use
Same as intended use.

5. Substantial Equivalence

	Candidate device	Predicate device
Proprietary name:	HemoCue® Hb 801 System	HemoCue® Hb 301 System
Common name:	Hemoglobin analyzing system	Hemoglobin analyzing system
510(k) number	/	K061047
Product code	GKR	GKR
Classification	Class II	Class II
Regulation	21 CFR 864.5620 Automated hemoglobin system	21 CFR 864.5620 Automated hemoglobin system
Classification Panel	Hematology	Hematology

The most important similarities and differences between the HemoCue® Hb 801 System (Candidate Device) and HemoCue® Hb 301 System (Predicate Device) are listed in the table below.

Characteristic	HemoCue® Hb 801 System (Candidate device)	HemoCue® Hb 301 System (Predicate device)
Analyzer		
Microcuvette		

Characteristic	HemoCue® Hb 801 System (Candidate device)	HemoCue® Hb 301 System (Predicate device)
Similarities		
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
Measuring principle	Spectrophotometric	Same
Reagent	No active ingredients	Same
Calibration	The system is traceable to the hemiglobincyanide (HiCN) method, according to ICSH. The system is factory calibrated and needs no further calibration.	Same
Quality control	Internal self-test (verifying analyzer performance)	Same
Differences		
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 (BLE) • USB	Serial port
Microcuvette insertion technique	"Slot in"	Tray

Characteristic	HemoCue® Hb 801 System (Candidate device)	HemoCue® Hb 301 System (Predicate device)
		
User interface	• Display • Beeper • Two buttons • Status LED	• Display • Beeper • One button

6. Measuring principle

Spectrophotometric

7. Standard/Guidance Referenced

- 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 EP37; Supplemental Tables for Interference Testing in Clinical Chemistry - First Edition
- CLSI EP09-A3; Measurement procedure comparison and Bias Estimation Using Patient Samples; 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 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 (Second Edition), Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic medical equipment.

- Electromagnetic Compatibility according to FCC CFR 47 Part 15

- IEC 62304:2006 (First Edition), Medical device software - Software life cycle processes

- ISO 14971:2007 (Second Edition), Medical devices - Application of risk management to medical devices

8. Performance Characteristics (if/when applicable)

1. Analytical performance

a. Precision – Whole Blood

Whole blood precision study was conducted with the purpose to verify repeatability, reproducibility, within-laboratory and between lot and site precision of the HemoCue® Hb 801 System by using venous K_2EDTA whole blood samples. This study was divided in two different parts, *Part 1* a multi-microcuvette lots and *Part 2* a multi-site test to evaluate repeatability, within laboratory precision and reproducibility.

Multi-microcuvette study was performed at a single site over 5 operating day. Six hemoglobin levels were analyzed with 5 separate runs testing 5 replicates with three lots of HemoCue® Hb 801 Microcuvette and one HemoCue® Hb 801 Analyzers. Each blood sample was analyzed with 25 replicates per microcuvette lot, providing 75 measurements for each level.

Multi-site study was performed at 3 sites during 5 operating days. Six hemoglobin levels were analyzed with five separate runs testing five replicates at each site using three HemoCue® Hb 801 Analyzers and one lot of HemoCue® Hb 801 Microcuvette. Each blood sample was analyzed with 25 replicates using one analyzer per site, providing 75 measurements for each level.

Table 1: Overall precision based on all HemoCue® Hb 801 microcuvette lots

Hb level (g/dL)	Mean (g/dL)	Repeatability		Within Lab Precision		Reproducibility	
		SD (g/dL)	CV (%)	SD (g/dL)	CV (%)	SD (g/dL)	CV (%)
2.0-3.0	2.43	0.05	-	0.05	-	0.05	-
6.0-7.0	6.55	0.07	-	0.08	-	0.08	-
9.5-10.5	9.96	-	0.68	-	0.71	-	1.11
13.5-14.5	14.07	-	0.71	-	0.82	-	1.16
16.5-17.0	16.87	-	0.60	-	0.73	-	0.95
23.0-24.0	23.39	-	0.67	-	0.77	-	0.97

Table 2: Overall precision based on all sites

Hb level (g/dL)	Mean (g/dL)	Repeatability		Within Lab Precision		Reproducibility	
		SD (g/dL)	CV (%)	SD (g/dL)	CV (%)	SD (g/dL)	CV (%)
2.0-3.0	2.30	0.03	-	0.04	-	0.05	-
6.0-7.0	6.55	0.07	-	0.07	-	0.08	-
9.5-10.5	10.24	-	1.04	-	1.17	-	1.63
13.5-14.5	13.91	-	0.71	-	0.75	-	1.00
16.5-17.0	16.75	-	0.52	-	0.63	-	0.66
23.0-24.0	23.35	-	0.74	-	0.74	-	0.89

b. Precision – Quality Control Material

A precision study was conducted at three sites over 20 operating days using three HemoCue® Hb 801 Microcuvette lots (one lot per site), three HemoCue® Hb 801 Analyzers (one analyzer per site), and 1 lot of control material (level 1= low, level 2= medium, level 3= high). Each control set was run in duplicate twice daily for 20 days, by 10 operators (minimum 2 operators per site).
A total of 240 measurements (80 per level) were generated at each site. SD and CV calculated for repeatability, between-run, between-day and within laboratory precision for each level were within the defined acceptance criteria. Also, SD and CV calculated for repeatability, within-laboratory precision and reproducibility combined for all sites per level were within the defined acceptance criteria.

Table 3: Overall precision, based on all sites, all microcuvette lots, all operators and all days per level

Control Level	Mean Value (g/dL)	Number of results	Repeatability		Within Lab/site Precision		Reproducibility	
			SD (g/dL)	CV (%)	SD (g/dL)	CV (%)	SD (g/dL)	CV (%)
Low	6.34	240	0.05	0.7	0.04	0.7	0.06	0.9
Medium	11.50	240	0.05	0.4	0.05	0.5	0.06	0.5
High	15.36	240	0.15	1.0	0.16	1.0	0.17	1.1

c. Linearity

A linearity study was conducted using hemoglobin concentration prepared from a single, venous whole blood sample. A total of 9 hemoglobin concentration (0.50, 3.78, 7.05, 10.33, 13.60, 16.88, 20.15, 23.43, 26.70 g/dL) spanning the claimed measuring range of the HemoCue® Hb 801 Analyzer (1.0-25.6 g/dL) were tested with 15 replicates and analyzed using three HemoCue® Hb 801 Analyzers (5 replicates/analyzer) and one lot of HemoCue® Hb 801 Microcuvette.
The statistical analysis was performed separately for each analyzer using a polynomial regression analysis using first, second and third order fits. Statistical testing was used to determine the polynomial model with the best fit by examining the standard error of the regression, S_{yx}.

The HemoCue® Hb 801 System is linear in the range 1.0-25.6 g/dL with fulfilled acceptance criteria for the non-linear error.

d. Shelf -life

HemoCue® Hb 801 Microcuvette shelf-life was determined by using 3 lots of HemoCue® Hb 801 Microcuvette. At every analysis run, the microcuvettes were tested with 3 venous K_2EDTA whole blood samples from 3 different subjects at each Hb level (a total of 9 fresh blood samples per analysis run). The shelf life of the HemoCue® Hb 801 Microcuvette is determined to 6 months (at time of premarket notification, will be extended)

e. Detection limit

Limit of Blank (LoB)

To determine Limit of Blank (LoB), plasma samples were obtained from four individual whole blood samples. The study was conducted with 3 HemoCue® Hb 801 Analyzers and 2 lots of HemoCue® Hb 801 Microcuvette over 4 operating days. One sample was analyzed each day at 3 different runs separated by at least 2 hours between each run. Two replicates/analyzer were analyzed at each run, in total 72 replicates/microcuvette lot. The data from both microcuvette lots were combined and the Anderson Darling normality test showed a non-normal distribution of the measuring results. The rank position was calculated according to the non-parametric option, using α-error 0.05 (yields p =0.95). 72 measurements resulted in a rank position of 68.9. LoB for the HemoCue® Hb 801 System was determined to be 0.26 g/dL.

Limit of Detection (LoD)

To determine Limit of Detection (LoB), four K_2EDTA whole blood samples were collected from different subjects. Four independent samples were prepared and the Hb-levels were within 1-5 times the LoB value and distributed within the range 0.46 - 1.0 g/dL. The study was conducted over 4 operating days using 3 HemoCue® Hb 801 Analyzers and 2 lots of HemoCue® Hb 801 Microcuvette. Four samples were analyzed where one sample was analyzed each day at 3 different runs with at least 2 hours between each run and with 2 replicates/analyzer and run, totally 72 replicates/microcuvette lot. The data has been evaluated and showed to have equal variance and LoD was established with a β-error at 0.05. LoD for the HemoCue® Hb 801 System was determined to be 0.3 g/dL.

Limit of Quantification (LoQ)

To determine Limit of Quantification (LoQ), four K_2EDTA whole blood samples were collected from different subjects. Four independent samples were prepared and the Hb-levels of the samples were slightly above LoD, within the range 0.40-0.52 g/dL. The study was conducted with 3 HemoCue® Hb 801 Analyzers and 2 lots of HemoCue® Hb 801 Microcuvette over 4 operating days. Samples were analyzed within the interval of LoD+0.4 g/L, where one sample was analyzed each day at 3 different runs with at least 2 hours between each run and with 3 replicates /analyzer and run, totally 108 replicates /microcuvette lot. Total Error for each sample was calculated by using the RMS-model. The calculated TE for each microcuvette lot was reviewed against the

defined goal for TE 8≤ 0.5 g/dL. LoQ for the HemoCue® Hb 801 System was determined to be 0.5 g/dL.

f. Analytical specificity

The purpose of the interference studies was to evaluate the effect of potential interferents on the HemoCue® Hb 801 System.

The study was performed by adjusting Hb-levels of the K_2EDTA whole blood samples collected. Each sample was divided into a reference group and a test group containing potential interferent at the test concentration listed below.
For potential interferences from leucocytes and platelets, and certain patient conditions (Sickle cells, Polycythemia vera, Thalassemia/hypochromia and Anemia) the interference was evaluated by using a comparative procedure between the HemoCue® Hb 801 System and ICSH as a reference method.

The following substances have been tested at hemoglobin concentrations 10±0.5 and 20±1.0 g/dL. No interference was found at following concentrations of the substances tested.

Substance	Test concentration	Unit
Acetaminophen	1324	µmol/L
Ascorbic acid	342	µmol/L
Creatinine	442	µmol/L
HbCO	10	%
HbO_2	≤ 50	%
Hemolysis	10	g/L
Ibuprofen	2425	µmol/L
MetHb*	25	%
Platelets	2000	x 10^9/L
Total protein	15	g/dL
Salicylic acid	4.34	mmol/L
Simvastatin	49	µmol/L
Tetracycline	34	µmol/L
Triglycerides	1500	mg/dL
Urea	42.9	mmol/L
Uric acid	1.4	mmol/L
Warfarin	32.5	µmol/L

*Multiple concentrations of MetHb up to 25% were tested and did not interfere with hemoglobin measurement at Hb-level 10±0.5 or 20±1.0 g/dL.

Normal blood pH and above, up to 8, at Hb level 10±0.5 or 20±1.0 g/dL do not interfere with the system.

The following substances have been tested to determine the interfering concentration.

Substance	Concentration (unit)	Hb concentration (g/dL)	Result
Conjugated bilirubin	>23 (mg/dL)	10	Interfering*
	Up to 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*
Leucocytes	>260 x 10^9/L	6.8 – 14.7	Interfering*

* May give elevated results in higher substance concentrations.

g. Within Measurement Equivalence Tests: Anticoagulants

The purpose of this study was to demonstrate the equivalence between the anticoagulants K_2EDTA and Li-Heparin on the HemoCue® Hb 801 System. The study was conducted at two sites, over 5 operating days at each site, using one HemoCue® Hb 801 Analyzer and one lot of HemoCue® Hb 801 Microcuvettes. Each out of 120 subjects provided one fresh venous K_2EDTA and one fresh venous Li-Heparin whole blood samples. Additional samples were collected from 11 subjects to adjust Hb value to high and low Hb values. The regression analysis was performed by using replicate 1 from the sample in the Li-Heparin tube vs. replicate 1 from the sample from the K_2EDTA tube.

Both the K_2EDTA and Lithium Heparin samples fulfils the acceptance criteria regarding the correlation and bias between the two anticoagulants used on the HemoCue® 801 System.

h. Within Measurement Equivalence Tests: Capillary vs. Venous Sample

The purpose of this study was to verify the equivalency of venous and capillary whole blood samples on the HemoCue® Hb 801 System. Capillary and venous whole blood samples were collected from 40 subjects, within an as wide range as possible. Additional data points from 212 subjects were taken from the method comparison study. The regression analysis was performed by using replicate from the venous sample vs. replicate from the capillary sample from the same subject. The venous K_2EDTA blood sample was collected directly after collection of the capillary sample. Both the venous and capillary samples were within the defined acceptance criteria and showed equivalency when used on the HemoCue® Hb 801 System.

i. Assay cut-off

N/A

2. Method Comparison Study

a. Method comparison with predicate device

Method comparison studies were performed to evaluate the accuracy of the HemoCue® Hb 801 System in the hands of intended users in point-of-care facilities when testing capillary and/or venous blood from individuals 1 month of age and older. The studies were performed at five primary care settings in the US over 73 operating days.

The study included a total of 264 venous and 233 capillary whole blood samples. Both venous and capillary whole blood samples were tested at each site using the HemoCue® Hb 801 System and the predicate device, HemoCue® Hb 301 System (comparative method, in duplicate).
The studies were performed on six HemoCue® Hb 801 Analyzers and four lots of HemoCue® Hb 801 Microcuvette by 13 operators. 6 % of the total number of samples (28/497 samples) were adjusted (contrived) in order to cover the lower and upper ends of the HemoCue® Hb 801 System's Analytical Measuring Range (AMR).

The results for all venous samples respectively all capillary samples are summarized in the table below. Linear regression analysis demonstrated comparable performance between the HemoCue® Hb 801 System and HemoCue® Hb 301 System.

Table 4: Method comparison study overall summary, all sites combined

Sample type	Total n =	Contrived n =	Slope (95% CI)	Intercept (95% CI)	r
K_2EDTA Venous	264	28	1.00 (0.99 to 1.01)	-0.14 (-0.26 to -0.03)	1.00
Capillary	233	NA	1.07 (1.02 to 1.12)	-0.91 (-1.54 to -0.28)	0.96

In addition, 71 pediatric samples were tested at one European clinical laboratory site over 7 operating days. Each blood sample was analyzed with 2 replicates on the HemoCue® Hb 801 System, with 2 replicates on the predicate device HemoCue® Hb 301 System, and with 3 replicates with the reference method ICSH.

Regression analysis demonstrated comparable performance between the HemoCue® Hb 801 System and ICSH and between the HemoCue® Hb 801 System and HemoCue® Hb 301 System.

In the linear regression analysis of the relationship between HemoCue® Hb 801 System and reference method ICSH, have a slope 0.95 and a correlation coefficient (r) 0.99.

In the linear regression analysis of the relationship between HemoCue® Hb 801 System and the predicate device HemoCue® Hb 301 System, have a slope 0.97 and a correlation coefficient (r) 0.99.

Both the venous and capillary samples were within the defined acceptance criteria. HemoCue® Hb 801 System provides a quantitative Hb measurement in both venous and capillary whole blood samples for adults and children above 1 month old and support use at point-of-care settings.

b. Matrix comparison

For Within Measurement Equivalence Tests on Anticoagulants and Capillary vs. Venous sample, refer to "Performance Characteristics" Section above.

3. Clinical studies

a. Clinical Sensitivity
N/A

b. Clinical specificity
N/A

c. Other clinical supportive data (when a. and b. are not applicable):
N/A

4. Clinical cut-off

N/A

5. Reference range

Reference ranges were verified by testing whole blood specimens collected and tested at 5 point-of-care locations in the US on the HemoCue® Hb 801 System. The values of the collected samples have been compared against the reference ranges to assess if the obtained values fall within the expected pediatric and adult reference intervals[1,2].
The study results verified that the reference ranges data on the HemoCue® Hb 801 System for the subgroups fall within the defined reference ranges below.

Table 5: Defined reference range

Subject group	Age	Hb, g/dL
Infant	>1 month -2 years	9.4 – 14.1
Child	>2 – 12 years	11.0 – 15.5
Adolescent	>12 – 21 years	10.9 – 15.1
Adult Male	>21 years	13.0-17.0
Adult Female	>21 years	12.0-15.0

[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*

6. Instrument name

HemoCue® Hb 801 System

7. System Description

a. Mode of operation

The HemoCue® Hb 801 System provides a direct reading of the hemoglobin concentration in a sample using specially designed, single use microcuvette and an analyzer.

The microcuvette serves both as a pipette and as a measuring cuvette. No dilution or other preparation of the blood sample is required before filling of the microcuvette. A whole blood sample of approximately 10 µL is drawn into the cavity in the microcuvette by capillary action.

The measurement takes place in the analyzer, which measures the absorbance of whole blood at an Hb/ HbO_2 isosbestic point. The measurement is performed directly on the whole blood through measurement of the transmitted and scattered light and using an algorithm for translation into the hemoglobin concentration of the sample.

The HemoCue® Hb 801 System is be traceable to the hemiglobincyanide (HiCN) method, the international reference method according to ICSH for the determination of the hemoglobin concentration in blood.

b. Software

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is "moderate" level of concern.

c. Specimen Identification

There is no specimen identification function for the HemoCue® Hb 801 System.

d. Specimen Sampling and Handling

A whole blood sample of approximately 10 µL is drawn into the cavity in the HemoCue® Hb 801 Microcuvette by capillary action. To perform a hemoglobin reading, a filled microcuvette is inserted into the microcuvette holder in the HemoCue® Hb 801 Analyzer.

e. Calibration

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

f. Quality Controls

The HemoCue® Hb 801 Analyzer has an internal quality control, a self-test. It automatically verifies that the optronic unit of the analyzer is working properly every time the analyzer is turned on, when the microcuvette holder is put back into place after removal, and every hour when in use.

If an external quality control is required by local or other regulations, commercially available controls recommended by HemoCue should be used.

8. Other Supportive Instrument Performance Characteristics Data Not Covered In the "Performance Characteristics" Section above

Cleaning and Disinfection Study
A cleaning and disinfection study was conducted to validate virucidal efficacy using the selected disinfectant with the recommended disinfection protocol. Super Sani-Cloth®Germicidal Disposable Wipe (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 two-minutes exposure at room temperature.
A robustness study was performed to demonstrate that the HemoCue® Hb 801 System is robust to multiple cleaning and disinfection cycles by using Super Sani-Cloth® Germicidal Disposable Wipe.

9. Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21CFR Part 809.10.

10. Conclusion

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