510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K201217

B Applicant

HemoCue AB

C Proprietary and Established Names

HemoCue® Hb 301 System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKR	Class II	21 CFR 864.5620 - Automated Hemoglobin System	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

To expand the age of the target population from adults to ≥ 1 month old when the device is used in primary care settings.

B Measurand:

Hemoglobin

C Type of Test:

Quantitative, photometric

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The HemoCue® Hb 301 System is intended for quantitative determination of hemoglobin in primary care or blood donation settings.

The HemoCue® Hb 301 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old in primary care setting.

The HemoCue® Hb 301 System is intended to be used to determine the hemoglobin concentration for adults in blood donation setting.

The HemoCue® Hb 301 System is for professional in vitro diagnostic use only.

C Special Conditions for Use Statement(s):

For Prescription Use Only

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

The HemoCue Hb 301 System provides a direct reading of the hemoglobin concentration in a sample using single-use microcuvettes and a photometer (analyzer). The HemoCue Hb 301 System consists of the following components:

- An analyzer supporting the following features:
  - Photometric determination of hemoglobin
  - Presentation of results on a display
- Power supply by power adapter or batteries
- Single use microcuvettes made of polystyrene plastic which do not contain reagents or active ingredients

B Principle of Operation:

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/HbO2 isosbestic point. The analyzer measures at two wavelengths (506 and 880 nm) in order to compensate for turbidity. 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 301 System is traceable to the hemiglobincyanide (HiCN) method, the international reference method according to International Council for Standardization in Hematology (ICSH) for the determination of the hemoglobin concentration in blood.

C Instrument Description Information:

1. Instrument Name:

   HemoCue® Hb 301 System

2. Specimen Identification:

   There is no specimen identification function for the HemoCue Hb 301 system.

3. Specimen Sampling and Handling:

   The HemoCue 301 microcuvette draws a small amount (approximately 10µL) of venous or capillary blood by capillary effect. The filled microcuvette is inserted into the microcuvette holder in the HemoCue Hb 301 analyzer.

4. Calibration:

   The HemoCue Hb 301 System is factory calibrated and needs no further calibration.

5. Quality Control:

   The HemoCue Hb 301 Analyzer has an internal quality control, a self-test. Every time the analyzer is turned on, it will automatically verify the system performance. This test is performed at regular intervals if the analyzer remains switched on.

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

V Substantial Equivalence Information:

A Predicate Device Name(s):

HemoCue® Hb 801 System

B Predicate 510(k) Number(s):
K181751

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201217	K181751
Device Trade Name	HemoCue Hb 301 System	HemoCue Hb 801 System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The HemoCue Hb 301 System is intended for quantitative determination of hemoglobin in primary care or blood donation settings. The HemoCue Hb 301 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old. The HemoCue Hb 301 System is for professional in vitro diagnostic use only.	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.
Patient population	Adults, adolescents, children, and infants above 1 month old	Same
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

General Device Characteristic Differences		
Sample type	Capillary, venous or arterial whole blood	Capillary or venous whole blood
Measuring range	0-25.6 g/dL	1-25.6g/dL
Connectivity	Serial port	• Wireless Bluetooth Low Energy (BLE) • USB
Microcuvette insertion technique	Tray	"Slot in"
User interface	• Display • Beeper • One button	• Display • Beeper • Two buttons • Status LED

VI Standards/Guidance Documents Referenced:

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

The HemoCue Hb 301 System was previously cleared under K061047 for adults in the primary care setting and BK060048. The purpose of the current 510(k) submission is to expand the age of the target population from adults to ≥ 1 month old. The previously submitted analytical performance studies are documented in K061047 and BK060048.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   The sponsor conducted a method comparison study in which 71 venous and capillary pediatric samples were analyzed on the HemoCue Hb 301 system, HemoCue Hb 801 system, and reference method ICSH. The reference hemiglobincyanide (HiCN) method used by HemoCue AB is a manual method set up according to CLSI H15-A3 Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard – Third Edition.

   Deming regression analyses were performed to estimate the parameters of the regression model (i.e. slope, intercept, 95% confidence intervals). The results of this comparison study are provided in the table below.

Parameter	N	Sample Range Tested	Slope	Intercept	r
Hemoglobin (g/dL)	71	6.4 g/dL – 22.8 g/dL	0.982	0.023	0.992

2. Matrix Comparison:

Refer to K061047

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Refer to K061047

F Other Supportive Instrument Performance Characteristics Data:

A secondary comparison study was performed with the HemoCue Hb 301 system and the HemoCue Hb 801 system. This study involved the same pediatric samples as those described in Section B.1 above. Deming regression analyses were performed to estimate the parameters of the regression model (i.e. slope, intercept, 95% confidence intervals). The results of this comparison study are provided in the table below.

Parameter	N	Sample Range Tested	Slope	Intercept	r
Hemoglobin (g/dL)	71	6.4 g/dL – 22.8 g/dL	1.015	-0.196	0.99

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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