5.0 510(k) Summary

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Date of Preparation:	August 2nd 2006
Proprietary Name:	HemoCue Hb 301 system
Classification Name:	Automated and Semi-Automated Hematology Devices, Automated hemoglobin system (21 CFR § 864.5620), Product code: GKR
Common Name:	Hemoglobin analyzing system
Equivalent to:	HemoCue AB claims substantial equivalence to the current legally marketed devices HEMOCUE Hb 301 SYSTEM (K061047) and HEMOCUE DONOR Hb CHECKER SYSTEM (BK030020)

5.1 Description

The HemoCue Hb 301 system consists of a small and portable analyzer (photometer) and plastic microcuvettes. The microcuvette serves both as a pipette and as a measuring cuvette. A blood sample is drawn into the cavity by capillary action. The filled microcuvette is inserted into the HemoCue Hb 301 Analyzer. The measurement takes place in the analyzer, which measures the absorbance of whole blood at a Hb/HbO_2 isobestic point. The system is factory calibrated and needs no further calibration.

5.2 Intended use

The HemoCue Hb 301 system is designed for quantitative point-of-care whole blood hemoglobin determination in primary care or blood donation settings 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.

5.3 Technological Characteristics

The technological characteristics for HemoCue Hb 301 system are equivalent to the predicate devices. The system consists of an analyzer (photometer) together with microcuvettes. The

microcuvette is made of polystyrene plastic and contains no active ingredients. The microcuvette serves both as a pipette and as a measuring cuvette and is for single-use only. A blood sample of approximately 10 µL is drawn into the cavity by capillary action.

The measurement takes place in the analyzer, which measures the absorbance of whole blood at a Hb/HbO2 isobestic point. The analyzer measures at two wavelengths (506 and 880 nm) in order to compensate for turbidity. The Hb/HbO_2 isobestic point at the wavelength 506 nm is defined as the optimal wavelength for determination of the hemoglobin concentration with the HemoCue Hb 301 system. The wavelength has been chosen with regard to the spectra characteristics, cavity depth of the microcuvette and possible interfering hemoglobin substances such as methemoglobin and carboxyhemoglobin.

The HemoCue Hb 301 System is calibrated against the hemiglobincyanide (HiCN) method, the international reference method for the determination of the hemoglobin concentration in blood. The system is factory calibrated and needs no further calibration.

5.4 Similarities with predicate devices

Claim	Similarities
Intended use	Quantitative point-of-care hemoglobin determination in primary care or blood donation settings using a specially designed analyzer and specially designed microcuvettes. The HemoCue systems are for In Vitro Diagnostic use only.
Result	Quantitative
Positioning	Point of Care
Analyte	Hemoglobin
Specimen	Whole blood
Labeling	Equal Directions For Use

5.5 Assessment of Performance

Studies were conducted in-house, in clinical laboratory settings and point of care centers to demonstrate the performance of the HemoCue Hb 301 system and that the intended user can easily operate the system and obtain results as expected.

5.5.1 Summary of Linearity study

The linearity of the HemoCue Hb 301 system was tested according to the NCCLS document EP6-A "Evaluation of the Linearity of Quantitative Measurement Procedure" using one batch of HemoCue Hb 301 Microcuvettes, five Hemocue Hb 301 Analyzers and three EDTA whole blood samples each prepared to seven haemoglobin concentrations in the range 0-25 g/dL. The EDTA whole blood samples were analyzed with four replicates on each HemoCue Hb 301 analyzers. As a reference method all levels were as well analyzed in duplicates with the international reference method ICSH. The HemoCue Hb 301 system is linear between 2-25 g/dL (within 4% difference at 2-5 g/dL and within 3% difference at 5-25 g/dL).

5.5.2 Summary of Precision study

The within-run and total precision for the HemoCue Hb 301 system was determined according to the NCCLS document EP5-A "Evaluation of Precision Performance of Quantitative Measurement Methods". Three levels of commercially available hemoglobin control material were analyzed, each level in duplicates, twice a day, during 20 operating days. Each level were analyzed at each run on five HemoCue Hb 301 Analyzers. Three different HemoCue Hb 301 Microcuvette batches were used. The data in table 1 was obtained for within-run and total precision of the HemoCue Hb 301 system.

Table 1:

Control level	N	Mean g/dL	Within run precision,		Total precision,	
			SD, g/L	CV, %	SD, g/L	CV, %
Low	400	7.3	0.059	0.82	0.066	0.91
Normal	400	13.2	0.106	0.80	0.122	0.92
High	400	17.2	0.135	0.78	0.152	0.88

5.5.3 Summary of Accuracy studies

The accuracy for the HemoCue Hb 301 system was determined by analyzing three batches of HemoCue Hb 301 Microcuvettes on four HemoCue Hb 301 Analyzers. Eight operators were performing the measurements. The International reference method ICSH was used for the comparison. The data in table 2 was obtained in the comparison performed.

Table 2:

N	Min (g/dL)	Max (g/dL)	Regression line	Correlation coefficient (r)
700	1.6	23.0	Y= 0.984x + 0.113	0.998

5.6 Conclusion

The HemoCue Hb 301 system is a convenient method for measuring whole blood hemoglobin and can be used by typical users and provide clinical results comparable to other test methods in current clinical laboratory and point-of-care practices.