

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

K041234

B. Purpose for Submission:

Special 510(k) for software modification for enhanced data management features.

C. Manufacturer and Instrument Name:

HemoCue® Hb 201 DM System

D. Type of Test or Tests performed:

Hemoglobin

E. System Descriptions:

1. Device Description:

The HemoCue® Hb 201 DM System consists of a portable, factory calibrated, dual wave, hand held photometer, and disposable microcuvettes containing dry reagents. The analyzer and microcuvettes must be used together as a system.

2. Principles of Operation:

The HemoCue technique is based on an optical measuring microcuvette of a small volume and a short light path. The microcuvette cavity contains reagents deposited on its inner walls. The blood sample is drawn into the cavity by capillary action and is mixed spontaneously with the reagents. The microcuvette is then placed in the HemoCue Hb 201 DM analyzer in which the transmittance is assured and the hemoglobin level calculated. The distance between the walls of the optical window is 0.130 mm. which permits photometric determination of hemoglobin in undiluted blood. The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrite converts the hemoglobin iron from the ferrous to the ferric state to form methemoglobin which then combines with azide to form azidemethemoglobin. The predicate device was modified by making the analyzer dimensions smaller. This was achieved by conveying the light over a plastic bridge, instead of reflecting it off a beam splitting mirror. The light itself has not been changed. The shape of the microcuvette was changed so that it will fit only in the Hb 201 DM analyzer.

3. Modes of Operation:

Manual load

4. Specimen Identification:

Automatic numbering

5. Specimen Sampling and Handling:
Capillary samples – microcuvettes are loaded by capillary action directly from fingerstick

Venous/Arterial-samples are collected into the appropriate anticoagulant (EDTA, heparin, or heparin/fluoride), mixed, and microcuvettes are loaded

6. Calibration:
Factory calibration

7. Quality Control:

The HemoCue® Hb 201 DM System has an internal electronic “self test” which automatically verifies the calibration of the instrument each time the analyzer is switched on and every second hour thereafter. Liquid quality control material is available for use on a daily basis.

8. Software:

FDA has reviewed the applicant’s Hazard Analysis and software Documentation: Yes or No

F. Regulatory Information:

1. Regulation Section:
21 CFR 864.5620
2. Classification:
II
3. Product Code:
GKR
4. Panel:
81 Hematology

G. Intended Use:

1. Indication(s) for Use:
The quantitative determination of hemoglobin in capillary, venous or arterial whole blood.
2. Special Condition for use Statement(s):
Point-of-care

H. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) numbers:

HemoCue® Hb 201 + System (K032203)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended use	The quantitative determination of hemoglobin in capillary, venous or arterial whole blood	same
Samples requirements	10 µl blood	same
Methodology	Modified Vanzetti	same
Differences		
Item	Device	Predicate
Software	Enhanced memory, docking station and PC software	600 result memory

I. Standard/Guidance Document Referenced (if applicable):**J. Performance Characteristics:**1. Analytical Performance:

- a. *Accuracy:*
- b. *Precision/Reproducibility:*
- c. *Linearity:*
- d. *Carryover:*
- e. *Interfering Substances:*

2. Other Supportive Instrument Performance Data Not Covered Above:

As required for a Special 510(k), the Sponsor has provided a risk analysis as well as a Declaration of Conformity with Design Controls indicating that development activities were conducted under appropriate design controls procedures, and the overall product specifications were met.

K. Conclusion:

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