510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K032482

B. Analyte:
Hemoglobin

C. Type of Test:
Quantitative, photometric measurement of hemoglobin

D. Applicant:
Stanbio Laboratory

E. Proprietary and Established Names:
HemoPoint® H2 Hemoglobin Measurement System and HemoPoint® H2 Cuvettes

F. Regulatory Information:

1. Regulation section:
   21 CFR 864.5620, Automated hemoglobin system
2. Classification:
   Class II
3. Product Code:
   GKR
4. Panel:
   Hematology (81)

G. Intended Use:

1. Indication(s) for use:
   The HemoPoint H2 Hemoglobin Measurement System is indicated for the quantitative determination of hemoglobin in arterial, venous, or capillary whole blood of adults, infants, and children in a professional point-of-care setting. The microcuvettes part number 3010-100 is indicated for use in the Hemopoint® H2 Hemoglobin Measurement System and HemoCue® B-Hemoglobin Photometer.
2. Special condition for use statement(s):
   The microcuvettes are intended to be used only once and must be disposed of after use as potentially infectious waste.
3. Special instrument Requirements:
   N/A

H. Device Description:
The HemoPoint H2 Hemoglobin Measurement System is comprised of a HemoPoint H2 Hemoglobin Photometer and HemoPoint H2 disposable Cuvettes.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   HemoCue B-Hemoglobin System with microcuvette (K961312)
   HemoCue Photometer (K832020)

2. Predicate K number(s):
   See above section.
3. Comparison with predicate:

Similarities			
Item	**Device**	**Predicate 1**	**Predicate 2**
Intended Use	Quantitative determination of hemoglobin	Same	Same
Sample Requirements	Venous, arterial, or capillary blood	Same	Same
Methodology	Modified azide methemoglobin Hct=estimation from hemoglobin	Hgb=Same Hct=None	Hgb=Same Hct=None
Differences			
Item	**Device**	**Predicate 1**	**Predicate 2**
Data Handling	Time/Data logging and data storage capability	Only with data management module	Only with data management module

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

1. *H3-A4 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard-Fourth Edition, NCCLS.*
2. *H4-A4 Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard-Fourth Edition, NCCLS.*
3. *H11-A3 Procedures for the Collection of Arterial Blood Specimens; Approved Standard, NCCLS*
4. *H15-A3 Reference and Selected Procedures for the quantitative Determination of Hemoglobin in Blood; Approved Standard-Third Edition, NCCLS.*
5. *EP9-A2 Method comparison and Bias Estimation Using Patient Samples; Approved Standard-Second Edition, NCCLS.*
6. *EP5-An Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline, NCCLS.*

K. Test Principle:

The device uses a modified azide methemoglobin method (Vanzetti) to measure hemoglobin.

A small amount of blood is loaded into the microcuvette via capillary action. The cuvette is then inserted into the HemoPoint H2 photometer where the color produced by the chemical reaction in the cuvette is measured. Results are displayed by LED readout.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

	Hemo Point H2 Cuvette In HemoPoint Device		HemoPoint H2 Cuvette In HemoCue device	
	With-in Run (CV)	Total (CV)	With-in Run (CV)	Total (CV)
Hemoglobin/Low (10.7g/dL	0.9%	1.1%	0.6%	0.8%
Hemoglobin/Normal (12.9g/dL)	0.7%	1.1%	0.8%	1.0%
Hemoglobin/High (17.3g/dL)	0.6%	1.2%	0.6%	0.9%

b. Linearity/assay reportable range:
0-25.6 g/dL

c. Traceability (controls, calibrators, or method):
Device calibrated against NCCLS reference method

d. Detection limit:
N/A

e. Analytical specificity:
N/A

f. Assay cut-off:
N/A

2. Comparison studies:

a. Method comparison with predicate device:
Comparison to NCCLS H15-A3 (y=0.023+1.006x, R=0.999, N=174 [duplicate measurements])

Comparison to predicate HemoCue (y=0.233+1.001x, R=0.998, N=286 [duplicate measurements])

Comparison of HemoPoint H2 cuvettes in Hemocue predicate (y=0.139+0.986x, R=0.999, N=286 [duplicate measurements])

b. Matrix comparison:

Capillary Samples. 4 sites (y=0.946x+0.3742x, R^2=0.8256, N=275)
Venous Samples, 4 sites (y=1.0005x-0.2334x, R^2=0.9962, N=286)
Arterial samples, 1 site (y=0.9868x-0.285, R^2=0.997x, N=10)

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:

5. Expected values/Reference range:
Expected values were based on the medical literature:

Women: 12.0-16.0 g/dL
Men: 13.0-17.5 g/dL
Children, depending on age: 9.0-24 g/dL

M. Conclusion:

Stanbio Laboratory has demonstrated that the HemoPoint H2 Hemoglobin Measurement System is substantially equivalent to the HemoCue B-Hemoglobin System.