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

A. 510(k) Number: #K042379

B. Purpose for Submission: New Over-the-counter (OTC) device

C. Manufacturer and Instrument Name: Applied Tech Products, LLC; BioSafe® Laboratories, Inc. AnemiaPro™ Self-Screener Hemoglobin Test Kit

D. Type of Test or Tests Performed: Quantitative hemoglobin test

E. System Descriptions:

1. Devise Description: The AnemiaPro™ Self-Screener device contains a single, unit-use disposable meter, enclosed in a foil pouch. It is a self-contained nitrocellulose based test strip, in plastic housing, that is divided into sections that read from 8 – 15 g/dL. It has an application membrane that contains a green indicator dye; and a quality control indicator adjacent to the fill port. The device also has an injection plunger, coated with a dilute solution of porcine sodium heparin (~ 6 U) to inhibit coagulation, and Tween 80® in a methanol and water base (to facilitate blood flow through the migration path). The kit also includes sterile alcohol, gauze pads and adhesive bandages; disposable safety lancets; a Transport Bag; and specimen collection instructions.

2. Principles of Operation: Red blood cells (RBC's) are separated from a sample of capillary whole blood by a microporous membrane (a separation matrix) designed for lateral flow assays to produce plasma. The nitrocellulose membrane, with open pore structure, allows efficient flow of viscous liquids. The membrane alters the flow of RBC's through the matrix, such that the lateral flow rate of plasma is greater than that of the RBC's. The amount of plasma generated is dependent upon the red cell mass (hematocrit) of the sample. A green dye is added to the membrane prior to separation of the whole blood, so that the plasma retains the color and becomes visible. The plasma migrates through the test strip, such that low hemoglobin allows more plasma (and high hemoglobin allows less plasma) to be separated from the whole blood sample. More plasma generates further migration distance; less plasma generates a shorter migration distance from the membrane. Therefore, migration distance is linear and inversely proportional to the hemoglobin concentration.

3. Modes of Operation: Manual, hand-held meter.

4. Specimen Identification: A single 50 uL drop of capillary whole blood is required for a 15 uL sample to charge the test strip.

5. Specimen Sampling and Handling: The fingerstick capillary sample is manually collected.

6. Calibration: The meter is precalibrated to predetermined whole blood hemoglobin concentrations, over the reportable range of 8 – 15 g/dL. Pointe Scientific Hemoglobin Calibrator (#K851432) and the Roche Modular Analyzer (#K953239), a HiCN method, were used in the calibration procedures.

7. Quality Control: There is a built-in quality control window, with an indicator dye, to assure that an adequate whole blood sample has been delivered from the application plunger to the test strip membrane. No color change indicates that an insufficient blood sample was added to the test strip.

8. Software: N/A

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes_____ or No_____

F. Regulatory Information:

1. Regulation section: 21 CFR 864.7500 – Whole Blood Hemoglobin Assays

2. Classification: Class II

3 Product code(s): KHG – Whole Blood Hemoglobin Determination; GIG - Hemoglobinometer

4. Panel: Hematology (81)

G. Intended Use:

1. Indication(s) for Use: The AnemiaPro™ Self-Screener is intended for OTC distribution, for the determination of hemoglobin concentration in a self-collected whole blood sample. The device is not intended for use in neonates.

2. Special Conditions for Use Statement(s): Over-the-counter (OTC); contraindicated for use in patients < 18 years of age.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers: Abbott Laboratories, Inc. Cell-Dyn Hematology Analyzer (#K955715); HemoCue, Inc. ß-Hemoglobin Analyzer (#K961312).

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	The AnemiaPro device is for quantitative determination of hemoglobin in whole blood (WB).	The HemoCue ß-Hemoglobin Meter has the same intended use.
Sample type	Capillary WB	Same
Mode	Hand-held	Same
Endpoint reading	≤ 30 minutes	Same

Differences		
Item	Device	Predicate
Technology	Lateral flow membrane separation of red blood cell mass from plasma	Colorimetric (modified Drabkins)
Sample types	Capillary WB	Capillary or venous WB
Reagents	None	Self-contained within cuvettes
Mode	Manual	Semi-automated
Reportable range	8 – 15 g/dL	0 – 25 g/dL

I. Special Control/Guidance Document Referenced (if applicable): ODE Guidance Document, Assessing the Safety and Effectiveness of Home-Use *In Vitro* Diagnostic Devices (IVD's); and NCCLS Documents:

1. H4-A3, Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens by Skin Puncture, Approved Standard – 3rd Edition.

2. GP10-A, Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristics (ROC) Plots; Approved Guideline.

3. EP7-P, Interference Testing in Clinical Chemistry; Proposed Guideline.

4. EP9-A, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, 2nd Edition.

5. EP5-T2, Evaluation of Precision Performance of Clinical Chemistry Devices; 2nd Edition.

6. EP12-A, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline, 2nd Edition.

7. Procedures for the Handling and Transport of Diagnostic Specimens and Etiologic Agents; Approved Standard, 3rd Edition.

8. EP6-A, Evaluation of the Linearity of Quantitative Analytical Methods.

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy: The AnemiaPro (Anemia Meter) was compared to a HiCN-based photometric reference method and the Cell-Dyn Analyzer on patient samples (N=40), over the reportable range of 8 – 15 g/dL. Regression statistics were:

HiCN	**Cell-Dyn**
y = 0.9153x + 0.5549	y = 0.9759x – 0.2935
r = 0.969; R2 = 0.9389	r = 0.931; R2 = 0.8664

b. Precision/Reproducibility: Within-run precision was determined using replicates (N = 5) tested on (3) hemoglobin levels over the range of the meter. Results ranged from 4.8 – 6.0 % CV.

Between-run precision was also determined using replicates (N = 5), but were tested over a period of (4) days to give a total of (N = 20). Results ranged from 5.1 – 6.0 % CV.

c. Linearity: Metered venous blood (N = 26), with predetermined hemoglobin concentrations, was allowed to migrate to endpoint, between 8 – 15 g/dL on (2) devices. Hemoglobin values, ranging 8.7 – 15.3 g/dL were plotted against migration distances between 23.7 – 5.1 mm. Results yielded this inverse linear regression equation: y = - 2.6851x + 45.551; R2 = 0.9487.

d. Carryover: N/A

e. Interfering Substances: Interference studies were performed on (4) replicates, each of lipids, bilirubin, hemoglobin (free), and protein (viscosity). Six standard dilutions of these substances were tested. Studies demonstrated there was no interference for lipids up to 600 mg/dL; for bilirubin, up to 40 mg/dL; for hemoglobin, up to 13.3 g/dL; and for protein, between 5 – 15 g/dL.

2. Other Supportive Instrument Performance Data Not Covered Above: An analytical accuracy and specificity study was done on males (< and ≥14.0 g/dL) and females (< and ≥ 12.0 g/dL). The results showed 96.3% analytical specificity /95.9% accuracy for males; and 98.9% specificity/97.1% accuracy for females. Overall specificity = 97.7%; and accuracy = 96.4%. The study was done on capillary samples with the Anemia Meter vs venous blood on the Cell Dyn device.

Clinical studies were performed at (3) sites, located in Chicago, IL, Denver, CO and Tucson, AZ on lay user samples (N = 224). A series of comparison studies were performed between the Anemia Meter, the Cell-Dyn and HemoCue devices over a range of 5.9 – 18.2 g/dL. These significant data were generated when the Anemia Meter (capillary self-testing) was compared to:

a. Cell-Dyn (venous professional testing)
   Slope = 0.924; Intercept = 1.082 ; CC = 0.929
b. HemoCue (capillary self-testing)
   Slope = 0.674; Intercept = 4.190; CC = 0.735
c. Anemia Meter (capillary professional)
   Slope = 0.890; Intercept = 1.490; CC = 0.945

Out of a total of (267) untrained lay user participants, 265 (99.2%) successfully self-collected a blood sample; and 224 had successful test outcomes (84.8%)

Sample environmental studies (test strip position; temperature/humidity; plunger depression) were performed. Endpoint studies were also done to support a stability of (1) month from the testing date.

K. Proposed Labeling:

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

L. Conclusion:

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