

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

**A. 510(k) Number:**

K041202

**B. Purpose for Submission:**

New Device

**C. Analyte:**

Fecal Occult Blood (FOB)

**D. Type of Test:**

Qualitative

**E. Applicant:**

WHPM, Inc.

**F. Proprietary and Established Names:**

Hemosure™ One-Step Fecal Occult Blood (FOB) Test; Occult Blood Test

**G. Regulatory Information:**

1. Regulation section:  
CFR Section 864.6550 – Occult Blood Test
2. Classification:  
Class II
3. Product Code:  
KHE
4. Panel:  
Hematology (81)

**H. Intended Use:**

1. Intended use(s):  
The Hemosure™ One-Step FOB Test is a rapid, immunochemical device for in vitro diagnostic use in qualitative determination of fecal occult blood by laboratories or physician's offices.
2. Indication(s) for use:  
Same as above; and it is useful to determine gastrointestinal (GI) bleeding found in a number of GI disorders, e.g., diverticulitis, colitis, polyps and colorectal cancer.
3. Special condition for use statement(s):  
N/A

4. Special instrument Requirements:  
N/A

**I. Device Description:**

The Hemosure™ One-Step FOB Test is a sandwich immunoassay; and employs a combination of monoclonal and polyclonal antibodies (MAB and PAB) to selectively identify human hemoglobin (hHb) in test samples with a high degree of sensitivity. It consists of a:

- Test Cassette, individually sealed in a foil pouch, containing a combination of mouse MAB and sheep or goat PAB, directed against human hemoglobin (hHb);  
and
- Fecal Collection Tube of extraction buffer, 2.0 mL.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Alfa Scientific Designs, Inc. Instant-View FOB (II) Test
2. Predicate K number(s):  
#K021423
3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Test type	One-step sandwich immu - noassay	Same
Antibodies (poly- clonal and mono- clonal)	Anti-human hemoglobin; and goat anti-mouse IgG	Same
Sample type	Feces	Same
Sensitivity	50 ng hHb/mL	Same
Test window	5 – 10 minutes	Same
Format	Cassette	Same
<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Number of tests/kit	(1) test	(20) tests
Indicator color	Pink-rose	Burgundy

**K. Standard/Guidance Document Referenced (if applicable):**

N/A

**L. Test Principle:**

The test cassette consists of a pad containing mouse anti-hHb antibodies conjugated to colloidal gold; a nitrocellulose strip containing a test line (anti-hHb antibodies); and a control line of goat anti-mouse IgG antibodies. As the test sample flows or migrates, via capillary action, through the absorbent test strip, a labeled antibody-dye conjugate binds to human hemoglobin (hHb) in the specimen. An antibody-antigen complex forms, binds to the anti-hHb antibody in the positive test reaction zone, and produces a pink-rose color band for hHb  $\geq 50$  ng/mL. In the absence of hHb, no line is produced in the positive test reaction zone. The control line binds the conjugated mouse antibodies regardless of the hHb concentration. A pink-rose color in the control reaction zone demonstrates that the device and reagents are functioning correctly.

**M. Performance Characteristics (if/when applicable):**1. Analytical performance:a. *Precision/Reproducibility:*

Samples (N=100) spiked with varying levels of hHb, ranging from 0 – 2000 ng/mL, were tested, at (3) sites, with (3) lots of tests. At the 50 ng hHb/mL cut-off, Lot 1 yielded (3) false (-) results; and Lots 2 and 3 yielded (1) false (-) result.

b. *Linearity/assay reportable range:*

No prozone effect was seen up to 2000 ng hHb/mL

c. *Traceability (controls, calibrators, or method):*

Mouse monoclonal and polyclonal anti-human hemoglobin antibodies

d. *Detection limit:*

A limit of 50 ng hHb/mL buffer or 50 ug hHb/g feces was determined using samples (N=50), spiked with levels of hHb that ranged 0 2000 ng hHb/ml. They were tested in-house with the proposed and predicate devices. There was agreement of > 99%.

e. *Analytical specificity:*

Interference testing was performed on aqueous samples with and without 50 ng hHb/mL. Substances tested included aqueous extracts of fruits and vegetables; 20 mg/mL solution of horseradish peroxidase; and toilet water with cleaner and deodorizer. Cross reactivity was tested on (9) species of animal hemoglobins, using diluted human fecal samples. No false results were obtained.

f. *Assay cut-off:*  
50 ng hHb/mL buffer

2. Comparison studies:

a. *Method comparison with predicate device:*

Three lots of the Hemosure and (1) lot of the Alfa assay were tested, in-house, on fecal samples (N=50) spiked with hHb to 1, 37.5, 50, 62.5 and 2000 ng hHb/mL. Both devices gave 30 (+) and 20 (-) readings for > 99% agreement.

b. *Matrix comparison:*

N/A

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):*

The study on samples (N=100) tested in-house, was also performed at (2) independent sites: a POL and a reference lab. The blinded study used (3) test lots. Stool samples were spiked with hHb at 1, 37.5, 50, 62.5 and 2000 ng hHb/mL. Percent (%) agreement ranged from 95 - > 99%, for an overall agreement of 98%.

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Negative (<50 ug hHb/g feces)

**N. Conclusion:**

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