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

A. 510(k) Number:
K070660

B. Purpose for Submission:
Marketing in the U.S.

C. Analyte:
Human Hemoglobin

D. Type of Test:
Fecal Occult Blood

E. Applicant:
Alfa Scientific Designs, Inc.

F. Proprietary and Established Names:
INSTANT-VIEW® Fecal Occult Blood (FOB) Rapid Test
Fecal Occult Blood (FOB) Rapid Test

G. Regulatory Information:

1. Regulation section:
   864.6550 Occult blood test
2. Classification:
   Class II
3. Product Code:
   KHE
4. Panel:
   Hematology

H. Intended Use:

1. Intended use(s):
   The INSTANT-VIEW® Fecal Occult Blood (FOB) Rapid Test is a qualitative immunoassay for the detection of Fecal Occult Blood by non-professional, lay individuals as an over-the-counter product for home use. Measurement of FOB is a useful as an aid to detect blood in stool as found in a number of gastrointestinal disorders, e.g. diverticulitis, colitis, polyps, and colorectal cancer. It is intended for over-the-counter use.

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2. Indication(s) for use:
   N/A
3. Special condition for use statement(s):

N/A

4. Special instrument Requirements:
   N/A

I. Device Description:

The INSTANT-VIEW® Fecal Occult Blood (FOB) Rapid Test is a one-step lateral flow chromatographic immunoassay. The test strip is contained in a cassette and consists of a burgundy-colored conjugate pad containing colloidal gold coupled with mouse anti-human hemoglobin monoclonal antibodies and a nitrocellulose membrane containing a test line (T line) and a control line (C line). The T line is coated with anti-human hemoglobin antibodies, and the C line is coated with goat anti-mouse IgG antibodies.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Beckman Coulter, Inc. Hemoccult® Fecal Occult Blood Test
2. Predicate K number(s):
   K880499
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended use	Qualitative detection of occult blood in feces	Same
Sample Type	Feces	Same
Differences		
Item	**Device**	**Predicate**
Detection method	Immunochromatographic assay	Chemical guaiac based assay
Analyte	Human hemoglobin	Hemoglobin
Users	Healthcare professionals and lay persons (OTC)	Healthcare professional use

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

N/A

L. Test Principle:

This test kit is one-step lateral flow chromatographic immunoassay. The test consists of three burgundy colored conjugate pads containing mouse anti-hHb antibodies conjugated with colloidal gold and a nitrocellulose membrane containing the test line. The human hemoglobin line appears as a visible burgundy line if the concentration of hHb in the specimen at or above 50 ng/ml.

A fecal sample is collected and prepared for testing in a sample collection tube containing extraction buffer. The extracted sample is added directly to the test device and migrates by capillary action through the test strip. If the level of hemoglobin in the fecal specimen is at or above the cutoff concentration, the T line appears as a visible burgundy line. If the level of hemoglobin in the fecal specimen is below the cutoff, no T line develops.

The control line is a internal procedural control. Goat anti-mouse IgG is used for the "Control Line" coating. When the gold conjugate reagent flows to the "Control Line" area, the goat anti-mouse IgG reacts to form a burgundy colored band regardless of the presence of hemoglobin.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*

        Human stool extraction samples were spiked with hHb at the following concentrations: 0, 37.5, 50, 62.5, and 500 ng/ml. 4 samples were tested at each concentration with three lots of the Alfa-Scientific FOBT. Samples with concentrations below 50 ng/ml hHb tested negative with the candidate device while samples at and above 50 ng/ml tested positive.

    b. *Linearity/assay reportable range:*
    N/A

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

        Internal Control: Procedural controls are included in the test device. A magenta line appearing the control region in considered as internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
        External Control: Controls are not provided with this kit. It is recommended that positive and negative controls be performed to verify proper test performance.

    d. *Detection limit:*

        The minimal detection limit is 50 ng/ml of hHb in buffer or 50 μg hHb/g in stool.

    e. *Analytical specificity:*

        Positive and negative stool samples were spiked with the following substances: Beef, chicken, fish (meat extract), horse, goat, pig, rabbit, and sheep hemoglobin; horseradish peroxidase; red radish; raw turnip; cauliflower; broccoli; parsnip; cantaloupe; Vitamin C; and iron. Addition of these substances had no effect on the test results.

    f. *Assay cut-off:*

2. Comparison studies:
    a. *Method comparison with predicate device:*

a. Forty human stool extraction samples were spiked with hHb at the following concentrations: 0, 37.5, 50, 62.5, and 500 ng/ml. The candidate device was compared to the predicate at each of the concentrations and agreed 100% of the time with the predicate and the expected results.
b. The candidate device was evaluated at three physician office laboratories and one medical laboratory by personnel with diverse educational backgrounds and work experience. One hundred human stool extraction samples were spiked with hHb at the following concentrations: 0, 37.5, 50, 62.5, and 500 ng/ml. (20 at each concentration) Results obtained from three POL sites agreed 97.7% with the expected results and results from the medical laboratory agree 99% with the expected results. Overall agreement was 98%.
c. The candidate device was evaluated in a consumer study of 120 lay individuals with various educational levels. 120 hHB spiked phosphate buffer saline (PBS) samples at the following concentrations: 0, 37.5, 62.5 and 500 ng/ml, were tested. Consumer results agreed 95% with the expected results, while professional results agreed 100% with the expected results.

b. Matrix comparison:

3. Clinical studies: N/A
   a. Clinical sensitivity:

   b. Clinical specificity:

   c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off: N/A

5. Expected values/Reference range:

Negative

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