Alfa Scientific Designs, Inc.
Wen Hua Fan
RA Specialist
13200 Gregg St
Poway, California 92064

February 15, 2018

Re: K173212
Trade/Device Name: Instant-view-plus immunochemical Fecal Occult Blood Test
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: KHE
Dated: January 11, 2018
Received: January 16, 2018

Dear Wen Hua Fan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kelly Oliner -S

For,
Lea Carrington
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173212

Device Name

Instant-view-plus™ Immunochemical Fecal Occult Blood Test

Indications for Use *(Describe)*

The Instant-view-plus™ Immunochemical Fecal Occult Blood Test is a qualitative immunoassay for detection of Fecal Occult Blood. It is intended for professional and over the counter use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Safety and Effectiveness as Required by 21 CFR 807.92

Date Prepared: February 8, 2018

Manufacture and Submitter: Alfa Scientific Designs, Inc.
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Contact Person: Wen Hua Fan, Ph.D.
E-mail: wfan@alfascientific.com

Device Name:

Trade Name : Instant-view plus™ Immunochemical Fecal Occult Blood Test
Common Name: Fecal Immunochemical Test
Classification Name: Occult Blood Test
Classification: Class II
Product Code: KHE

Predicate Device: K070660 and K021423

Device Description: This device is a Driven Flow™ chromatographic immunoassay consisting of a test strip housed in a plastic cassette.

Device Characteristics in Comparison with the Predicate Devices:

Similarities			
Item	Device Instant-view-plus™ Immunochemical Fecal Occult Blood Test, K173212	Predicate Instant-view® Fecal Occult Blood (FOB) Self-Test K070660	Predicate *Instant-view*™ Fecal Occult Blood Rapid Test K021423
Intended use	The Instant-view-plus™ Immunochemical Fecal Occult Blood Test is a qualitative immunoassay for detection of Fecal Occult Blood. It is intended for professional and over the counter use.	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. The 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,	This Fecal Occult Blood (FOB) Rapid Test is an immunochemical device intended for the qualitative detection of Fecal Occult Blood by laboratories or physicians' offices. It is useful to determining gastrointestinal (GI) bleeding found in a number of gastrointestinal (GI) disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer. This test is recommended for use in 1) routine physical examinations, when hospital patients are first admitted, 2) hospital monitoring for bleeding in patients, 3) screening for colorectal cancer or gastrointestinal bleeding &om any source.

Similarities			
Item	Device Instant-view-plus™ Immunochemical Fecal Occult Blood Test, K173212	Predicate Instant-view® Fecal Occult Blood (FOB) Self-Test K070660	Predicate *Instant-view*™ Fecal Occult Blood Rapid Test K021423
		polyps, and colorectal cancer. It is intended for over-the-counter use.	
Sample type	Human feces (mixed with detection buffer)	Same	Same
Assay cut-off	50 ng/ml (human hemoglobin in human fecal sample in extraction buffer)	Same	Same

Differences			
Item	Device Instant-view-plus™ Immunochemical Fecal Occult Blood Test, K173212	Predicate Instant-view® Fecal Occult Blood (FOB) Self-Test K070660	Predicate *Instant-view*™ Fecal Occult Blood Rapid Test K021423
Test principle	Chromatographic immunoassay using Driven Flow™ Technology	Lateral flow chromatographic immunoassay	Lateral flow chromatographic immunoassay
Test device	Cassette	Cassette and dip strip	Cassette and dip strip
Assay Reading Time	Between 1-10 minutes	4-7 minutes	5-10 minutes

Test Principle:

This assay is a Driven Flow chromatographic immunoassay. The device consists of one test strip in a plastic cassette. The test strip consists of:

- A burgundy colored conjugate pad treated with mouse anti-hHb antibodies conjugated with colloidal gold.

- A strip of nitrocellulose membrane with a Test line (T-line) and a Control line (C-line). The T-line is coated with anti-hHb antibodies, and the C-line is coated with goat anti-mouse IgG antibodies.

When an adequate volume of test specimen is dispensed into the sample well of the device, the test specimen migrates across the test strip. If the concentration of hHb in the specimen is at or above 50 ng/ml, the T-line appears as a visible burgundy line. The intensity of the T-line may vary according to the concentration of the hHB in the samples. If the concentration of hHb in the specimen is below the detectable level, no T-line develops. The C-line is coated with goat anti-mouse antibody, which binds to the conjugated monoclonal antibody, regardless of the presence of hHb in the sample.

Precision/Reproducibility:

Repeatability was evaluated using three lots of devices, in-house by two trained laboratory professionals. For repeatability Hb-free fecal samples were collected and spiked with human whole blood with known hemoglobin levels to achieve the following six fecal hemoglobin concentrations: 0 ng/ml, 25 ng/ml, 50 ng/ml, 55 ng/ml, 60 ng/ml, and 500 ng/ml. Fifty replicates were performed for each concentration level.

	Positive Percent Agreement (#Positive/#Total) (95% CI)	Negative Percent Agreement (#Negative/#Total) (95% CI)
Lot 1	100% (164/164) (97.8%, 100%)	100% (136/136) (97.3%, 100%)
Lot 2	100% (164/164) (97.8%, 100%)	97.8% (133/136) (93.7%, 99.5%)
Lot 3	100% (164/164) (97.8%, 100%)	99.3% (135/136) (96.0%, 99.9%)
Combined Lots	100% (492/492) (99.3%, 100%)	99% (404/408) (97.5%, 99.7%)

Reproducibility was conducted across three intended use sites using three device lots (same three lots at all sites), and three operators (one at each site) over a minimum of 5 days. For reproducibility Hb-free fecal samples were collected and spiked with human whole blood with known hemoglobin levels to achieve the following nine fecal hemoglobin concentrations: 0 ng/ml, 25 ng/ml, 50 ng/ml, 55 ng/ml, 60 ng/ml, and 500 ng/ml. Fourteen replicates were performed for each sample and concentration level. Insure® FIT™ FOBT Controls (K101831) Negative and Positive Controls were also tested daily to ensure the validity of the test results.

Reproducibility - Lot Variability

Lot	Positive Percent Agreement (#Positive/#Total) (95% CI)	Negative Percent Agreement (#Negative/#Total) (95% CI)
Lot 1	100 % (684/684) (99.5%, 100%)	98.6% (568/576) (97.3%, 99.4%)
Lot 2	100 % (684/684) (99.5%, 100%)	97% (559/576) (95.3%, 98.3%)
Lot 3	100 % (684/684) (99.5%, 100%)	96.4% (555/576) (94.5%, 97.7%)

Reproducibility - Day Variability

Day	Positive Percent Agreement (#Positive/#Total) (95% CI)	Negative Percent Agreement (#Negative/#Total) (95% CI)
Day 1	100 % (410/410) (99.1%, 100%)	95.1% (329/346) (92.3%, 97.1%)
Day 2	100 % (410/410) (99.1%, 100%)	89% (308/346) (85.2%, 92.1%)
Day 3	100 % (410/410) (99.1%, 100%)	98.6% (341/346) (96.7%, 99.5%)
Day 4	100 % (410/410) (99.1%, 100%)	95.4% (330/346) (92.6%, 97.3%)
Day 5	100 % (410/410) (99.1%, 100%)	96.8% (335/346) (94.4%, 98.4%)

Reproducibility - Site Variability

Site	Positive Percent Agreement (#Positive/#Total) (95% CI)	Negative Percent Agreement (#Negative/#Total) (95% CI)
Site 1	100 % (684/684) (99.5%, 100%)	97.1% (559/576) (95.3%, 98.3%)
Site 2	100 % (684/684) (99.5%, 100%)	97.4% (561/576) (95.7%, 98.5%)
Site 3	100 % (684/684) (99.5%, 100%)	96.7% (557/576) (94.9%, 98%)

Prozone Effect Study:

The Prozone effect was evaluated using three device lots, by two operators testing Hb-free stool specimens spiked with human blood of known hemoglobin concentrations so as to obtain fecal test samples with different Hb concentrations: 1,000 ng/ml (1 ug/ml),

2,000 ng/ml (2 ug/ml), 3,000 ng/ml (3 ug/ml), 4,000 ng/ml (4 ug/ml), 5,000ng/mL (5 ug/ml), 50,000 ng/mL (50 ug/ml), and 500,000 ng/mL (500 ug/ml). Twenty aliquots of each sample concentration were mixed with extraction buffer in the specimen collection tubes and tested in a randomized order. The results show that Instant-view-plus™ Immunochemical Fecal Occult Blood Test was not affected by highly concentrated hemoglobin in specimen, no prozone effect was observed in the above Hb concentrations.

Stability Studies:

Insure® FIT™ FOBT Controls (K101831) Negative and Positive Controls were also tested daily to ensure and confirm the validity of the test results of the stability studies.

1. Test Kit Stability (Accelerated)

   The accelerated stability study was conducted with three lots of Instant-view-plus™ Immunochemical Fecal Occult Blood Test. Hb-free stool specimens were spiked with human blood (of known hemoglobin level) to obtain fecal samples containing six different hemoglobin concentrations: 0 ng/ml, 25 ng/ml, 50 ng/ml, 60 ng/ml, 72 ng/ml, and 500 ng/ml. Each hemoglobin concentration was tested with two devices from each lot. (2) operator tested the three lots stored at following four temperatures: 20°C (68°F), 23°C (73.4°F), 35°C (95°F), and 60°C (140°F) and test results were collected each day for 20 days. The test kit was determined to be stable for 24 months, when stored at the temperatures between 8 - 23°C (46.4 - 73.4°F).

2. Test Kit Stability (Real Time)

   The real time stability study was conducted with three lots of Instant-view-plus™ Immunochemical Fecal Occult Blood Test. Hb-free stool specimens were spiked with human blood (of known hemoglobin level) to obtain fecal samples containing six different hemoglobin concentrations: 0 ng/ml, 25 ng/ml, 50 ng/ml, 60 ng/ml, 72 ng/ml, and 500 ng/ml. Each hemoglobin concentration was tested with four devices from each lot. (2) operators tested the three lots stored at room temperature (20 ~ 23°C) for 26 months. The test kit was determined to be stable for at 24 months.

Analytical specificity:

Insure® FIT™ FOBT Controls (K101831) Negative and Positive Controls were also tested daily to ensure the validity of the test results.

<u>Specificity to human hemoglobin variant</u>
The ability of Instant-view-plus™ Immunochemical Fecal Occult Blood Test to detect human hemoglobin variants was determined by testing hemoglobin-A (HbA), hemoglobin-S (HbS) and hemoglobin-C (HbC) by preparing spiked stool samples containing seven different hemoglobin concentrations: 0 ng/ml, 40 ng/ml, 48 ng/ml, 50 ng/ml, 60 ng/ml, 72 ng/ml, and 500 ng/ml. (3) aliquots of each of the seven concentrations (7 HbA, 7 HbS and 7 HbC supernatants) of spiked stool test samples were

mixed with detection buffer in Instant-view-plus™ Immunochemical Fecal Occult Blood Test collection bottles. Samples were tested in a randomized order. Results showed Instant-view-plus™ Immunochemical Fecal Occult Blood Test equivalently recognizes variants of hemoglobin HbA, HbS and HbC.

Cross-Reactivity

Cross-reactivity of Instant-view-plus™ Immunochemical Fecal Occult Blood Test with animal hemoglobin was evaluated by testing prepared test samples by spiking Hb-free stool specimen with known levels of human Hb solution to obtain fecal samples with seven different Hb concentrations: 0 ng/ml, 40 ng/ml, 48 ng/ml, 50 ng/ml, 60 ng/ml, 72 ng/ml, and 500 ng/ml. Five replicates of spiked hemoglobin-negative stool concentrations listed above were then spiked with the intended level of respective animal hemoglobin such as beef (2000 μg/ml), chicken (500 μg/ml), fish (100 μg/ml), horse (500 μg/ml), goat (500 μg/ml), rabbit (500 μg/ml), pig (500 μg/ml), horseradish peroxidase (20,000 μg/ml), and sheep (100 μg/ml). All samples were tested in a randomized order. Instant-view-plus™ Immunochemical Fecal Occult Blood Test did not show significant cross-reactivity with any of the animal hemoglobins tested.

Interfering Substances

Susceptibility of Instant-view-plus™ Immunochemical Fecal Occult Blood Test to interference from extracts (vegetable) was evaluated by testing (5) replicates of prepared test samples by spiking Hb-free stool specimen with known levels of human Hb solution to obtain fecal samples with seven different Hb concentrations: 0 ng/ml, 40 ng/ml, 48 ng/ml, 50 ng/ml, 60 ng/ml, 72 ng/ml, and 500 ng/ml. The 5 replicates of the spiked hemoglobin-negative stool concentrations listed above were spiked with the intended level of respective vegetable extracts: broccoli extracts (100%), cantaloupe extract (100%), cauliflower extract (100%), parsnip extract (100%), red radish extract (100%), and turnip extract (100%). All samples were mixed with detection buffer in Instant-view-plus™ Immunochemical Fecal Occult Blood Test sample collection bottles and tested in a randomized order. Instant-view-plus™ Immunochemical Fecal Occult Blood Test did not show significant interference from any of the vegetable extracts.

Interfering Supplements

Susceptibility of Instant-view-plus™ Immunochemical Fecal Occult Blood Test to interference from iron and sodium L-ascorbate was evaluated by testing 3 replicates of prepared test samples by spiking Hb-free stool specimen with known levels of human Hb solution to obtain fecal samples with seven different Hb concentrations: 0 ng/ml, 40 ng/ml, 48 ng/ml, 50 ng/ml, 60 ng/ml, 72 ng/ml, and 500 ng/ml. The 3 replicates of spiked hemoglobin-negative stool concentrations were spiked with iron (0.5% (w/v), and sodium L-ascorbate (0.5% (w/v). All samples were mixed with detection buffer in Instant-view-plus™ Immunochemical Fecal Occult Blood Test sample collection bottles and tested in a randomized order. Instant-view-plus™ Immunochemical Fecal Occult Blood Test did not show significant interference from iron and sodium L-ascorbate.

Interference from Toilet Water

Susceptibility of Instant-view-plus™ Immunochemical Fecal Occult Blood Test to

interference from toilet water was evaluated by testing 40 replicates of prepared test samples by spiking Hb-free stool specimen with known levels of human Hb solution to obtain fecal samples with seven different Hb concentrations: 0 ng/ml, 40 ng/ml, 48 ng/ml, 50 ng/ml, 60 ng/ml, 72 ng/ml, and 500 ng/ml. Twenty replicates of spiked hemoglobin-negative stool concentrations were collected without toilet water and 20 replicates of spiked hemoglobin-negative stool concentrations were collected submerged with toilet water. All samples were mixed with detection buffer in Instant-view-plus™ Immunochemical Fecal Occult Blood Test sample collection bottles and tested in a randomized order. Instant-view-plus™ Immunochemical Fecal Occult Blood Test did not show significant interference from samples collected in toilet water.

Assay cut-off:

The cut-off value for the Instant-view plus™ Immunochemical Fecal Occult Blood (FOB) Test was validated in-house. Fecal test samples were prepared by spiking stool samples with human blood of known hemoglobin concentration, to obtain the following fecal hemoglobin concentrations: 0 ng/ml, 25 ng/ml, 50 ng/ml, 48 ng/ml, 60 ng/ml, 72 ng/ml and 500 ng/ml. Twenty aliquots of each of the seven concentrations of spiked stool test samples were tested in randomized order. Testing was performed side-by-side with the predicate by comparing the test results of the device with that of the predicate. The cut-off was determined to be 50 ng/ml (hemoglobin in fecal sample mixed with detection buffer).

Concentration	N	Instant-view-plus™ plus Immunochemical Fecal Occult Blood Test		Percent Positive	Percent Negative
		Positive	Negative		
0 ng/ml	20	0	20	0%	100.00%
				0% - 15.5%	84.5% - 100%
25 ng/ml	20	1	19	5%	95%
				0.80% - 19.80%	80.20% - 99.20%
48 ng/ml	20	11	9	55%	45%
				39.12% - 70.82	29.18% - 60.82%
50 ng/ml	20	11	9	55%	45%
				39.12% - 70.82	29.18% - 60.82%
60 ng/ml	20	20	0	100%	0%
				84.5% - 100%	0% - 15.5%
72 ng/ml	20	20	0	100%	0%
				84.5% - 100%	0% - 15.5%
500 ng/ml	20	20	0	100%	0%
				84.5% - 100%	0% - 15.5%

Method comparison with predicate device:

A method comparison of Instant-view plus™ Immunochemical Fecal Occult Blood (FOB) Test with the predicate test, *Instant-view*™ Fecal Occult Blood Rapid Test, was conducted by assessing 299 patient samples. The method comparison study was performed at three POC testing sites by two 2 operators at each site. The Insure® FIT™ FOBT Controls (K101831) Negative and Positive Controls were run prior to testing. Statistical analysis of site-wide test results as well as combined results showed that Instant-view plus™ Immunochemical Fecal Occult Blood (FOB) Test results have acceptable overall percent agreement as well as positive percent agreement and negative percent agreement with *Instant-view*™ Fecal Occult Blood Rapid Test. The method comparison study demonstrated that the analytical performance of the Instant-view plus™ Immunochemical Fecal Occult Blood (FOB) Test is substantially equivalent to the predicate device.

Study Site	Instant-view-plus™ Immunochemical FOB Test	Predicate Test: Instant-View Fecal Occult Blood Rapid Test			Negative Percent Agreement (95% CI)	Positive Percent Agreement (95% CI)	Overall Percent Agreement (95% CI)
		Positive	Negative	Total			
Site 1	Positive	36	1	37	98.5% (92.1%, 99.9%)	94.7% (82.3%, 99.4%)	97.2% (92.0%, 99.4%)
	Negative	2	67	69			
	Total	38	68	106			
Site 2	Positive	36	1	37	98.9% (93.8%, 99.9%)	97.3% (85.8%, 99.9%)	98.4% (94.3%, 99.8%)
	Negative	1	87	88			
	Total	37	88	125			
Site 3	Positive	25	1	26	97.6% (87.4%, 99.9%)	96.2% (80.4%, 99.9%)	97.1% (89.8%, 99.6%)
	Negative	1	41	42			
	Total	26	42	68			
Combined Sites	Positive	97	3	100	98.5% (95.6%, 99.7%)	6.0% (90.2%, 98.9%)	97.7% (95.2%, 99.1%)
	Negative	4	195	199			
	Total	101	198	299			

Consumer Study:

To support over the counter use, a consumer study was performed by testing Instant-view plus™ Immunochemical Fecal Occult Blood (FOB) Test with the predicate test, Instant-view® Fecal Occult Blood (FOB) Self-Test hemoglobin free feces spiked samples at the following concentrations: 0 ng/ml, 25 ng/ml, 50 ng/ml, 60 ng/ml, and 500 ng/ml.

Concentration (ng/mL)	Number of Samples	Predicate Device		New Device		Difference (New – Predicate)	
		Negative (%)	Positive (%)	Negative (%)	Positive (%)	Negative % (95% CI of Difference)	Positive % (95% CI of Difference)
0	54	54	0	54	0	0 (-6.8%, 6.8%)	0 (-6.8%, 6.8%)
25	54	52	2	53	1	1.9% (-6.8%, 1.1%)	-1.9% (-11.1%, 6.8%)
50	54	25	29	26	28	1.9% (-17.4%, 21.0%)	-1.9% (-21.0%, 17.4%)
60	54	1	53	1	53	0 (-8.6%, 8.6%)	0 (-8.6%, 8.6%)
500	54	0	54	0	54	0 (-6.8%, 6.8%)	0 (-6.8%, 6.8%)