K070660

Alfa Scientific Designs, Inc.

FDA Registered • ISO 9001/EN 46001 Certified
In-Vitro Diagnostic (IVD) Devices Manufacturer • Contract R&D • OEM

I.S. EN ISO 9001
I.S. EN 46001

JUN 21 2007

510(k) Summary

Safety and Effectiveness as Required by 21 CFR 807.92

Manufacture and Submitter	**Name:**	Alfa Scientific Designs, Inc.
	Address:	13200 Gregg Street Poway, CA 92064 Telephone (858) 513-3888 x 324 Fax: (858) 513-8388
	Contact Person:	Majid Pajouh, Ph.D. E-mail: mpajouh@alfascientific.com
Device Name	**Trade Name:**	*INSTANT-VIEW®* Fecal Occult Blood (FOB) Self-Test Fecal Occult Blood (FOB) Self-Test
	Common Name:	Immunoassay, FOB Test
	Classification:	Occult Blood Test
	Product Code:	NGK
Date of Summary Preparation		***December 25, 2006***
Predicate Device		510K Number: K880499 Hemoccult® test by Beckman Coulter, Inc.
Device Description		Device is a one-step lateral flow chromatographic immunoassay. The test strip in the device consists of 1) a burgundy-colored conjugate pad containing colloidal gold coupled with mouse anti-human hemoglobin monoclonal antibodies, and 2) 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.
Intended Use		The Fecal Occult Blood (FOB) Self-Test is a qualitative immunoassay for the detection of Fecal Occult Blood by non-professional, lay individuals as a self-test product. Measurement of FOB is useful as an aid to detect human 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.
Similarity to the Predicate Device	• Both are one-step rapid tests. • Both are intended to provide qualitative detection of human hemoglobin in the fecal specimen. • Both are in-vitro diagnostic devices. • The proposed device has a built-in quality control feature but predicate does not. • Since FOB is an immunologically based rapid test for the detection of human hemoglobin in the fecal samples, it has inherent advantages compared to the currently marketed chemically based fecal occult blood rapid tests including the predicate Hemoccult®. • FOB is more specific than Hemoccult® since it is specific for human hemoglobin and unlike Hemoccult® does not give false positive results due to consumption of red meats, etc.
Sensitivity and Specificity	The sensitivity of the proposed device is 50 ng/ml and it is specific for human hemoglobin.
Accuracy	One hundred (100) samples of hemoglobin free feces extraction specimens collected in-house were divided into 5 groups of 20 each. The five groups of extraction samples were spiked with human hemoglobin at five different concentrations (0, 37.5, 50, 62.5 and 2000 ng/ml. Those 100 specimens were tested in house with FOB and predicate device. The correlation between the FOB and the predicate device was 100%.
Reproducibility	This study was carried out at four (4) sites outside Alfa, three Physician's Office Laboratories (POL) and one Medical Laboratory. Evaluations at the POL sites were performed by personnel with different educational backgrounds and working experience and agreed **97.7%** with the expected results. The results obtained from the Medical Laboratory agreed **99%** with the expected results. FOB was also tested by 120 professional and non-professional lay individuals of different education, age and backgrounds **95%** of which were able to follow the package insert instructions and obtain accurate results obtained by professionals.
Stability	The test device is stable when stored in controlled environment at 15-30° C 59-86° F) for up to two years following the manufacturing or until the expiration date printed on the label, whichever comes first.

Formats of the Device	The proposed device has only cassette format. The cassette is a device that contains a dip-strip in a plastic housing.
Conclusion	The results of accuracy, specificity, sensitivity, reproducibility, cross reactivity, and interference studies demonstrate that the proposed test is substantially equivalent to the predicate device.
Consumer study	**Conclusion of the comparison between professionals and consumer studies:** Professional results agreed 100% with the expected results whereas consumer results agreed 95% with the expected results (four false negatives and two false positives). Consumer results are within the accepted range. The responses from consumers are very positive. Over 98% of the consumers found the *INSTANT-VIEW*® Fecal Occult Blood (FOB) Self-Test to be simple, fast, convenience and accurate. The results of the consumer study demonstrated that it is compatible and similar to the results obtained by professionals and as a result *INSTANT-VIEW*® Fecal Occult Blood (FOB) Self-Test is safe and effective device for over the counter use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 21 2007

Majid Pajouh, Ph.D.
Alfa Scientific Designs, Inc.
13200 Gregg Street
Poway, California 92064

Re: k070660
Trade/Device Name: *INSTANT-VIEW*® Fecal Occult Blood (FOB) Self-Test
Fecal Occult Blood (FOB) Self-Test
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: KHE
Dated: May 17, 2007
Received: May 21, 2007

Dear Dr. Pajouh:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070660

Device Name:

INSTANT-VIEW® Fecal Occult Blood (FOB) Self-Test

Indications For Use:

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Prescription Use_____ AND/OR Over-The-Counter Use____X__
(Pert 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K070660

Indications for Use

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Fecal Occult Blood (FOB) Self-Test

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