SEP 14 2011

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K110309

Submitted By: Zhejiang Orient Gene Biotech Co., LTD
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Date Prepared: January 28, 2011

Device Name Trade or Proprietary Name: Orient Gene Biotech – One Step Rapid FOB

Common or Usual Name: Fecal Occult Blood Test.

Regulation 21 CFR 864.6550

Classification Class II

Product Codes KHE

Panel: Hematology

Predicate Device: K070660 - INSTANT-VIEW® Fecal Occult Blood (FOB) Rapid Test

Device Description The FOB One Step Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The membrane is pre-coated with anti-hemoglobin antibody on the test line region of the device. During testing, the specimen reacts with the particle coated with anti-hemoglobin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibody on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Intended Use The FOB One Step Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in human fecal specimens.

The device is suitable for use in laboratories and physician's offices as well as for Over the Counter Use.

Indications for Use The FOB One Step Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in human fecal specimens. The device is suitable for use in laboratories and physician's offices as well as for Over the Counter Use.

SUBSTANTIAL EQUIVALENCE

The following tables summarize similarities and differences between FOB One Step Rapid Test and the current INSTANT-VIEW® Fecal Occult Blood (FOB) Rapid Test.

Item	INSTANT-VIEW® Fecal Occult Blood (FOB) Rapid Test Predicate	FOB One Step Rapid Test
Intended Use	The Instant-View® Fecal Occult Blood (FOB) Rapid Test is a rapid qualitative test for the immunochemical detection of fecal occult blood/human hemoglobin (hHb) in human fecal specimens as an aid in the diagnosis of gastrointestinal disorders such as: diverticulitis, colitis, polyps, and colorectal cancer. The device is suitable for use in laboratories and physician's offices as well as for home use.	The FOB One Step Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in human fecal specimens as an aid in the diagnosis of gastrointestinal disorders such as: diverticulitis, colitis, polyps, and colorectal cancer. The device is suitable for use in laboratories and physician's offices as well as for Over the Counter use.
Specimen	Fecal	Same
Sensitivity	0.05 µg hHb/mL	Same -50 ng hHb/mL
Storage	2 - 30°C	Same
Principle	Sandwich Immunochromatographic Assay	Same
Read Time	5 Minutes	5 minutes
Test Line	Membrane Immunoassay	**Colloidal Gold**

Performance Characteristics

The following are performance characteristics of FOB One Step Rapid Test

Detection limit:

The sensitivity of the device was tested by spiking 100 hemoglobin-free stool samples with varying concentrations (0, 37.5, 50, 62.5 and 2000ng hHb/ml) of human hemoglobin. The test shows a cut-off of 50ng hHb/mL of buffer solution and no pro-zone effect was seen up to 2000 ng hHb/ml of buffer solution. Result are summarized below:

hHb concentration (ng/mL)	Total	Positive	Negative
0	20	0	20
37.5	20	0	20
50.	20	20	0
62.5	20	20	0
2000	20	20	0

Potential Interferences

An interference study was carried out by adding known amounts of potential interfering substances to aqueous fecal samples that contain 0 and 50 ng /mL of human hemoglobin. Substances tested included horseradish peroxidase (20 mg/mL), aqueous extracts of red radish, raw turnip, cauliflower and broccoli, dietary supplements of chloride, fluoride, Vitamin C (ascorbic acid) and iron, and toilet water with and without cleaner and deodorizer.

Potential Cross Reactors:

A cross-reactivity study of animal hemoglobin was carried out by spiking negative(0 ng hHb /mL) and positive(50 ng hHb /mL) fecal samples with no reaction from beef hemoglobin, chicken hemoglobin, fish hemoglobin, horse hemoglobin, goat hemoglobin, pig hemoglobin, rabbit hemoglobin and sheep hemoglobin, respectively, at the concentration of 200 ng/mL.

REPRODUCIBILITY

Inter-Site

To evaluate reproducibility of the test, 75 hemoglobin-free fecal samples spiked with varying levels (0, 37.5, 50, 62.5, and 2000 ng hHg/mL) of human hemoglobin were tested at 3 medical laboratories with 3 lots of tests and run 5 times each lot at each site. The results are summarized below:

3 Sites	Total Results	Lot 1	Lot 2	Lot 3
Hb concentrations		P / N	P / N	P / N
0 ng/mL	45	0 / 15	0 / 15	0 / 15
37.5 ng//mL	45	0 / 15	0 / 15	0 / 15
50 ng/mL	45	15 / 0	15 / 0	15 / 0
62.5 ng/mL	45	15 / 0	15 / 0	15 / 0
2,000 ng/mL	45	15 / 0	15 / 0	15 / 0

Intra-Run

Intra-Run reproducibility was determined by testing 3 lots of test cassettes by spiking 50 hemoglobin-free fecal samples with varying levels(0, 37.5, 50,, 62.5, and 2000 ng hHg/ml) of human hemoglobin and run 10 times each. The results are summarized below:

	Total Results	Lot 1	Lot 2	Lot 3
Hb concentrations		P / N	P / N	P / N
0 ng/mL	30	0 / 10	0 / 10	0 / 10
37.5 ng//mL	30	0 / 10	0 / 10	0 / 10
50 ng/mL	30	10 / 0	10 / 0	10 / 0
62.5 ng/mL	30	10 / 0	10 / 0	10 / 0
2,000 ng/mL	30	10 / 0	10 / 0	10 / 0

Inter-Day

Day to day reproducibility study was carried out by testing cassettes from the same lot with 50 fecal samples spiked with varying levels (0, 37.5, 50, 62.5, and 2000 ng hHg/ml) of human hemoglobin on 3 consecutive days with 10 replicates each day. The results are summarized below:

3 days	Total Results	Lot 1	Lot 2	Lot 3
Hb concentrations		P / N	P / N	P / N
0 ng/mL	30	0 / 10	0 / 10	0 / 10
37.5 ng//mL	30	0 / 10	0 / 10	0 / 10
50 ng/mL	30	10 / 0	10 / 0	10 / 0
62.5 ng/mL	30	10 / 0	10 / 0	10 / 0
2,000 ng/mL	30	10 / 0	10 / 0	10 / 0

ACCURACY

A study was conducted to evaluate the Fecal Occult Blood Rapid Test and compare results with a commercially available Fecal Occult Blood Rapid Test at three physician office laboratories by technical personnel, and one medical laboratory by non-technical personnel with diverse educational backgrounds and ages.

Consumer results using the FOB One Step Rapid Test compared to both the professional and Predicate test results were evaluated:

Study of technical personnel

In each POL site, 100 human stool extraction samples were spiked with human hemoglobin at the following concentrations: 0, 37.5, 50, 62.5, and 500 ng/ml (20 replicates at each concentration). Results obtained from 3 sites agreed 99.0% with the expected results and 98.0% with results of predicated device.

Study of non-technical personnel

150 human stool extraction samples were spiked with hHb at the following concentrations: 0, 37.5, 50, 62.5, and 500ng/ml (30 at each concentration). Thirty (30) participants without technical background were enrolled to conduct the study in a medical laboratory. Each participant tested 5 samples (1 at each concentration) with the two FOB devices.

Tests (tester)	Total Evaluated Samples	Correct Results	Discrepant Results	Agreement
Orient Gene FOB Test Layuser vs. Expected	150	148	2	**98.7%**
Orient Gene FOB Test Layuser vs. Predicate test	150	147	3	**98.0%**
Orient Gene FOB technicians vs Expected	100	99	1	**99.0%**
Orient Gene FOB Technician vs Predicate test	100	98	2	**98.0%**

Results generated by 3 trained technicians with the Orient Gene FOB One Step Rapid Test as compared to the predicate test:

		Predicate test		Total Results
Orient Gene FOB Test	Results	Positive	Negative	
	Positive	59	1	60
	Negative	1	39	40
Total Results		60	40	100

Percent Positive Agreement = 59/60 = 98.3% (95% C.I. = 91.1% - 100%)
Percent Negative Agreement = 39/40 = 97.5% (95% C.I. = 86.8% – 99.9%)
Overall Agreement = 98/100= 98.0% (95% C.I. = 93.0% - 99.8%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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SEP 1 4 2011

Re: k110309
Trade/Device Name: FOB One Step Rapid Test
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: KHE
Dated: July 5, 2011
Received: July 27, 2011

Dear Mr. Lehnus:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110309

Device Name: FOB One Step Rapid Test

Indications For Use:

The FOB One Step Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in human fecal specimens. The device is suitable for use in laboratories and physician's offices as well as for home use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K110309