AUG 1 2 2004

510 (k) Summary

Date of Summary: 5 May 2004

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

Sponsor and Manufacturer
WHPM, Inc.
9440 Telstar Avenue, Unit 1
El Monte, CA 91731

Correspondent
Fran White
MDC Associates
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Devices
Manufacturer: Alfa Scientific Designs, Inc.
Product: Instant-View Fecal Occult Blood (FOB) II Test (Cassette).

Product Description
The Hemosure™ One-Step FOB Test is a lateral flow immunoassays intended for the detection of fecal occult blood.

Intended Use
The Hemosure™ One-Step Fecal Occult Blood (FOB) Test is an immunochemical device intended for the qualitative detection of Fecal Occult Blood by laboratories or physicians offices. It is useful to determine gastrointestinal (GI) bleeding found in a number of GI disorders, e.g. diverticulitis, colitis, polyps, and colorectal cancer.

Performance Characteristics
Neither dietary substances nor toilet water fresheners or cleansers interfere with the Hemosure™ One-Step FOB Test.
The Hemosure™ One-Step FOB Test gives positive results only when human hemoglobin with sufficient concentration is present. The Hemosure™ One-Step FOB Test does not cross-react with hemoglobin from other species.
Fifty extracted stool samples, free of human hemoglobin, were collected in house and then spiked with human hemoglobin (hHb) to the following concentrations: 0ng hHb/mL, 37.5ng hHb/mL (25% lower than cutoff), 50ng hHb/mL (cutoff), 62.5ng hHb/mL (25% higher than cutoff), and 2,000ng hHb/mL. All samples with concentrations of 50 ng hHb/mL or greater gave positive results. The results agreed 100% with predicate device. This indicates

Hemosure™ One-Step FOB Test has a sensitivity of 50 ng hHb/mL.
100 extracted stool samples, free of human hemoglobin, were collected in house and then spiked with human hemoglobin (hHb) to the following concentrations: 0ng hHb/mL, 37.5ng hHb/mL (25% lower than cutoff), 50ng hHb/mL (cutoff), 62.5ng hHb/mL (25% higher than cutoff), and 2,000ng hHb/mL. The samples were then blinded and tested with the Hemosure™ One-Step FOB Test. The studies were performed in three sites including a physician's office laboratory, a reference laboratory, and the W.H.P.M. Inc. laboratory.
The test results obtained from Physician's Office Laboratory agreed 97% with the expected results. The results obtained from the Reference Laboratory and W.H.P.M., Inc.'s Laboratory both agreed 99% with the expected results. Accordingly, the overall accuracy of the Hemosure One-Step Fecal Occult Blood Test is 98%.

Conclusion

The Hemosure™ One-Step FOB Test is substantially equivalent to Alfa Scientific Designs' Instant-View Fecal Occult Blood (FOB) II Test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

W.H.P.M., Inc.
c/o Ms. Fran White
Regulatory Consultant
MDC Associates
163 Cabot Street
Beverly, MA 01915

AUG 1 2 2004

Re: k041202
Trade/Device Name: Hemosure™ One-Step Fecal Occult Blood Test
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: KHE
Dated: July 13, 2004
Received: July 14, 2004

Dear Ms. White:

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97).

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 (301) 594-3084. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., 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: K041202

Device Name: Hemosure™ One-Step Fecal Occult Blood Test

Indication for Use:

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For professional use only.

Prescription Use ___X___ **AND/OR** **Over The Counter Use** ____
(21 CFR 801 Subpart D) **(21CFR807 Subpart C)**

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

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

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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