510(k) SUMMARY

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

510(k) Number: Designed (k) Number to be Determined

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Contact Person:

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Preparation Date:

December 08, 2006

Device Information:

Trade or Proprietary Name:
Forsure One Step Fecal Occult Blood (FOB) Screen Card Test

Common/Usual Name:
Lateral flow immunochromatographic assay for detection of human hemoglobin or fecal occult blood in feces

Device Classification Name:
Immunoassay of human hemoglobin or fecal occult blood

Regulatory Name:
Human Hemoglobin or Fecal Occult Blood (FOB) Test System

Regulation Section: 21 CFR § 866. 6550

Regulatory Class: Class II

Product Code: KHE

Panel: Hematology (81)

Predicate Devices:
Forsure One Step Fecal Occult Blood (FOB) Screen Card Test is substantially equivalent to WHPM Hemosure One Step Fecal Occult Blood (FOB) Test cleared by FDA (K041202) for its stated intended use.

Device Description:
Forsure One Step Fecal Occult Blood (FOB) Screen Card Test is a qualitative, sandwich colloidal gold conjugate immunoassay for the determination of human hemoglobin in feces. The method employs a unique combination of monoclonal antibodies to selectively identify hemoglobin in test sample with a high degree of sensitivity. In less than 5 minutes, elevated levels of human hemoglobin as low as 50 ng/ml can be detected, and positive results for high levels of hemoglobin can be seen in the test as early as two to three minutes. As the test sample flows through the absorbent device, the Colloidal Gold labeled antibody- conjugate binds to the hemoglobin in the specimen forming an antibody-antigen complex. This complex binds to another anti-hemoglobin antibody in the positive reaction zone and produces a pink-ross color band when hemoglobin concentration is greater than 50 ng/ml. In the absence of hemoglobin, there is no line in the positive reaction zone. The reaction mixture continues flowing through the absorbent device past the positive reaction zone and negative control zone. Unbind conjugate binds to the reagents in the negative control zone, producing a pink rose color band, demonstrating that the reagents and device are functioning correctly.
A **NEGATIVE** specimen produces one distinct color bands in control area. A **POSITIVE** specimen produces two color band in the control and test area. There is no meaning attributed to color or its intensity for either line.

Intended Use:
Forsure One Step Fecal Occult Blood (FOB) Screen Card Test is a rapid, immunochromatographic assay for the qualitative detection of intact hHb (human hemoglobin) in fecal specimens. It is a convenient and hygienic method for detecting human fecal occult blood, which may be in dicative of gastrointestinal disease associated with bleeding such as colorectal carcinoma, Crohn's disease, ulcerative colitis, and colon polyps in humans.

Comparison to Predicate Device(s):
Both devices (Forsure and WHPM) are for the qualitative determination of the Fecal Occult Blood. The specific antibodies against human hemoglobin were used in both devices. All test devices are visually –read single use device. The cutoff of each analyte is same (50 ng/ml or 50 μg/g of feces).

Summary:
The information provided in this pre-market notification demonstrates that Forsure One Step Fecal Occult Blood (FOB) Screen Card Test is substantially equivalent to WHPM Hemosure One Step Fecal Occult Blood (FOB) Test. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate devices. The information supplied in this pre-market notification provides reasonable assurance that the Forsure One Step Fecal Occult Blood (FOB) Screen Card Test is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

New Bay Bioresearch Company, Limited
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ATTN: Rodrigo Berlie

MAY 11 2007

Re: K063693
Trade/Device Name: Forsure One Step Fecal Occult Blood (FOB) Screen Card Test
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: KHE
Dated: December 11, 2006
Received: December 14, 2006

Dear Mr. Berlie:

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). 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., M.D., Ph.D.
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): K063693

Device name: Forsure One Step Fecal Occult Blood (FOB) Screen Card Test

Indications for Use:

Forsure One Step Fecal Occult Blood (FOB) Screen Card Test is a rapid, immunochromatographic assay for the qualitative detection of intact hHb (human hemoglobin) in fecal specimens. It is a convenient and hygienic method for detecting human fecal occult blood, which may be in dicative of gastrointestinal disease associated with bleeding such as colorectal carcinoma, Crohn's disease, ulcerative colitis, and colon polyps in humans.

Forsure One Step Fecal Occult Blood (FOB) Screen Card Test is an immunological test for both professional and over the counter use.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___√___ (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) K063693