

K063693
MAY 11 2007

510(k) Submission For
Forsure One Step Fecal Occult Blood (FOB) Screen Card Test
New Bay Bioresearch Co., Ltd.

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

Submitter:

Tianjin New Bay Bioresearch Co., Ltd.
#3 Jian She Rd, Ba Li Tai Industry Area Jin Nan District,
Tianjin, China
Telephone: 86-22-28751515
Facsimile: 86-222-875-1516

Contact Person:

Rodrigo Berlie
New Product Development Director
Telephone: (760) 828-0990
Facsimile: (760) 602-2999

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

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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 indicative 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).

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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.