K080812

Summary of Safety & Effectiveness
Hemoccult® ICT
Immunochemical Fecal Occult Blood Test Kit

1.0 **Submitted By:**

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JUN 25 2008

2.0 **Date Submitted:**

March 21, 2008

3.0 **Device Name(s):**

3.1 **Proprietary Names**
Hemoccult® ICT

3.2 **Classification Name**
Ocult blood test

4.0 **Predicate Device:**

Candidate(s)	Predicate	Manufacturer	Docket Number
Hemoccult ICT	Hemoccult ICT (formerly FlexSure OBT)	Beckman Coulter, Inc.	K961062

5.0 **Description:**

Hemoccult ICT (Immunochemical Fecal Occult Blood Test) is a rapid, visually read, qualitative immunochemical chromatographic method for detection of human hemoglobin in fecal samples. It incorporates multiple components including separate sample collection card(s), applicator sticks, test devices, buffer, patient instructions, physician instructions and product instructions for use.

6.0 **Intended Use:**

Hemoccult ICT (Immunochemical Fecal Occult Blood Test) is a rapid, visually read, qualitative immunochemical chromatographic method for detection of human hemoglobin in fecal samples.

Clinical Significance:

Fecal occult blood tests are useful screening aids for detecting primarily lower gastrointestinal (g.i.) disorders that may be related to iron deficiency anemia, diverticulitis, ulcerative colitis, polyps, adenomas, colorectal cancers or other g.i. lesions that can bleed. Hemoccult ICT is recommended for use by health professionals as part of routine physical examinations or when lower g.i. disorders are suspected.

7.0 **Comparison to Predicate(s):**

The following tables show the similarities and differences between the predicates identified in Section 4.0 of this summary.

Similarities to the Predicate

Product	Aspect/Characteristic	Comments
Hemoccult ICT	Intended Use	Same as Predicate HOICT
	Composition of Test Card Materials	Same as Predicate HOICT
	Buffer Solution	Same as Predicate HOICT
	Testing Procedure Methodology	Same as Predicate HOICT
	Sample Stability	Same as Predicate HOICT
	Analytical Performance	Same as Predicate HOICT
	Clinical Performance Source Data	Same as Predicate HOICT

Differences from the Predicate

Product	Aspect/Characteristic	Comments
Hemoccult ICT	Clinical Performance Data Presentation	Data provided in the new product instructions includes clinical performance for all three days evaluated during the original predicate clinical study.
	2-day Patient Screening Kit Labeling	A 2-day kit option is being created whereas the predicate only offered a 3-day kit.
	3-day Patient Screening Kit Labeling	The predicate Patient Screening Kit Labeling is now adding the specifications of being a 3-day kit.

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through intended use, material composition, formulation, and clinical performance data analysis.

Immunochemical fecal occult blood test positivity rates of approximately 2% should be expected in a screening population of average risk, asymptomatic individuals age 50 or older. The Hemoccult ICT was evaluated using multi-day fecal collections (all returned collections of the three dispensed slides regardless of number of days), one day fecal collections (day one results only), two day collections (day one and day two results) and three day collections (only those individuals who returned all three days of fecal collections). The positivity rate for multi-day collections was approximately 2% in a group of 88 young, presumed normal volunteers, ages 17-33, who did not follow a restricted diet. The Hemoccult ICT multi-day screening positivity rate and estimated positive predictive value for colorectal neoplasia were 1.8% and 15.6%, respectively, in a group of 1734 average risk individuals, ages 41-97, who followed a restricted diet. Among high risk patients, Hemoccult ICT multi-day screening had a clinical sensitivity of 90% for colorectal cancer and 28% for large adenomas; in this study, Hemoccult ICT had low sensitivity for non-neoplastic colorectal lesions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 2008

Beckman Coulter, Inc.
C/O Sylvia Zorich
200 South Kraemer Boulevard, W-110
PO Box 8000
Brea, California 92822

Re: k080812
Trade/Device Name: Hemoccult ICT
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: KHE
Dated: March 21, 2008
Received: March 24, 2008

Dear Ms. Zorich:

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

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 Part 801), 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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/industry/support/index.html.

Sincerely yours,

Maria M. Chan
for Dr Becker

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

Indication for Use

510(k) Number (if known): K080812

Device Name: Hemoccult® ICT

Indications For Use:

Hemoccult ICT (Immunochemical Fecal Occult Blood Test) is a rapid, visually read, qualitative immunochemical chromatographic method for detection of human hemoglobin in fecal samples. Fecal occult blood tests are useful screening aids for detecting primarily lower gastrointentinal (g.i.) disorders that may be related to iron deficiency anemia, diverticulitis, ulcerative colitis, polyps, adenomas, colorectal cancers or other g.i. lesions that can bleed. Hemoccult ICT is recommended for use by health professionals as part of routine physical examinations or when lower g.i. disorders are suspected.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080812