

Preamble

HemaPrompt is presently approved and being used by health care professionals for the screening of stool for occult blood. It is a guaiac based system using a color change in the test slide to show the presence of a pathological amount of blood in the stool, which indicates the need for further investigation by medical personnel.

Screening of stool for occult blood has been recommended by the American Cancer Society and accepted by a number of medical societies as a worthwhile tool to detect a number of gastro-intestinal diseases, with occult blood often present in such conditions as ulceration, diverticulitis and cancer. It should be carried out on a yearly basis as a screening test for those over fifty, and for monitoring those with a family history of bowel disease, those on chemotherapy, or those with post bowel surgery for cancer.

At the present time the majority of such tests require the patient to apply a stool specimen to a test card which then is returned to the physician, usually by mail in a special envelope, for development and interpretation. It has been estimated however that compliance is poor (less than 20% of test cards being returned to the physician by some estimates) possibly because of the lack of immediacy of results and the patients' unwillingness to send such material by mail.

Risk/ Benefit Considerations.

Benefits

The clinical benefit of early detection provided by HemaPrompt is a decrease in the death rate from complications caused by delayed diagnosis of bowel problems causing bleeding. By having the test performed at home one would expect increased compliance and decreased cost to the patient. The physician would still have to be notified of the results.

Risks

Since the test is typically used in asymptomatic subjects, and assuming normal co-operation of the patient in notifying the physician, delays in seeking treatment are no greater than presently encountered. There is a recognized false positive and false negative rate which is no different from the professionally used test.

Performance Considerations.

HemaPrompt for use at home is the same in configuration and chemical constitution as that currently used by professionals. HemaPrompt is much simpler and safer to use than similar home-use kits because the developing solution is individually contained in each slide thereby obviating the need to measure or handle a potentially hazardous solution. This design also obviates variations in user technique, and because of a "built - in" control monitor, proper function is obvious.

Utilizing the home - use kit and written instructions, the rate of a false reading of test results by the patient was similar to that obtained by professionals. This was demonstrated with a study involving a group of 250 lay persons (at different locations, over age 50, both genders, varying race and educational background) who were asked, after reading instructions, to perform the test and interpret the results. A group of 50 nurses who perform fecal occult blood tests routinely in a hospital was given the same exercise with minimal instruction. The results from the two groups showed no statistically significant variation in ability to perform the test and interpret results.

Labeling Considerations.

Each test kit (of three slides) has adequate directions for home-use purposes employing concise wording (SMOG at the 5 - 6 grade level), liberal use of step-by- step drawings, and a variety of colored illustrations demonstrating examples of positive and negative results. A questionnaire given to the 50 lay persons who had read these instructions, demonstrated a greater than 95% understandability rate on the most important question: "Should you see a physician if your test is positive ?" Several other questions were more difficult to understand and the test instructions were revised accordingly.

Conclusion

Lay persons are able to adequately perform a Fecal Occult Blood test in the home setting when used in the format provided by the HemaPrompt system.



SEP 15 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Robert Schreiber, M.D.
AERSCHER, Inc.
353 High Street
Chestertown, Maryland 21620

Re: K981661/S1
Trade Name: HemaPrompt
Regulatory Class: II
Product Code: KHE
Dated: June 23, 1998
Received: June 26, 1998

Dear Dr. Schreiber:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

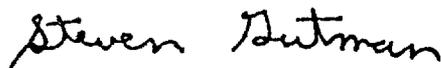
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number..... Pending

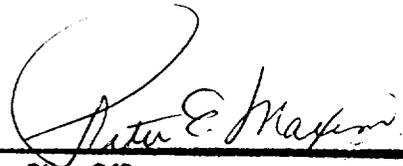
Device Name..... HemaPrompt

Indications For Use

HemaPrompt is a guaiac-based in-vitro slide method for the qualitative detection of occult blood in feces by lay persons.

It is a useful aid in the diagnosis or early detection of a number of gastrointestinal disorders, and is recommended for use in monitoring for recurrences of previously treated bowel conditions, and in screening for colorectal cancer or for other sources of gastro-intestinal bleeding.

For Over-The-Counter Use



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K-981661