K013857

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"Summary of Safety & Effectiveness"

The AimStep™ Pregnancy (Home Test) is intended for non-professional use for the identification of hCG (human Chorionic Gonadotropin) in urine to aid in the determination of pregnancy. The test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of hCG. The assay is conducted by adding urine to the test device and observing for the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody-hCG-colored conjugate and form a colored line on the "Test Region" of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line at the Control Region will always appear regardless of the presence or absence of hCG.

The AimStep™ Pregnancy test detects hCG concentrations of 20 mIU/ml and greater. The test has been standardized to the World Health Organization Third International Standard. The addition of hLH (300 mIU/ml), hFSH (1000 mIU/ml), and hTSH (1000 µIU/ml) to negative (0 mIU/ml hCG) and positive (20 mIU/ml hCG) urine showed no cross-reactivity.

A clinical trial was conducted comparing the results of AimStep™ Pregnancy to the Clearview™ Easy HCG Pregnancy Test. The study included 137 female participants and demonstrated an accuracy of over 99% correlation between the 2 tests. The results also showed that the majority of the participants found AimStep™ Pregnancy very easy to use, and that they had no trouble understanding the labeling, reading the instructions, or interpreting the results.

AimStep™ Pregnancy and the Clearview™ Easy HCG Pregnancy Test use the following similar methodologies and components:

a) Dry particle coated with anti-hCG which reacts with the specimen
b) Specimen migrates on a membrane coated with antibodies
c) A colored line appears in a Test Region to indicate a positive result
d) A colored line appears in a Control/Reference Region to indicate the test is completed and has worked correctly

AimStep™ Pregnancy and Clearview™ Easy HCG Pregnancy Test use the following different methodologies and components:

a) AimStep™ Pregnancy uses a colloidal gold particle and the predicate device uses a blue latex particle
b) AimStep™ Pregnancy produces a Pink colored line in the Test and Control Zones and the predicate device produces a Blue colored line in the Test and Reference region.

The overall results of the clinical trial confirm that AimStep™ Pregnancy (Home Tests) is a suitable test for over-the-counter pregnancy testing.

Martin O'Connor, Regulatory Affairs

01-16-02
Date

Premarket Notification 510(k) Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Martin O'Connor
Regulatory Affairs
Germaine Laboratories, Inc.
4139 Gardendale Center, Suite 101
San Antonio, TX 78229

JAN 2 2 2002

Re: k013857
Trade/Device Name: AimStep™ Pregnancy
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: November 20, 2001
Received: November 21, 2001

Dear Mr. O'Connor:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

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

Indications For Use

510(k) Number: K013857

Device Name: AimStep™ Pregnancy

"Indications For Use" - AimStep™ Pregnancy is intended for non-professional use for the qualitative identification of hCG (human Chorionic Gonadotropin) in urine to aid in the determination of pregnancy.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013857

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109) or Over-The-Counter Use ✓