NOV 1 2002

K022681

510(k) SUMMARY

DEVICE NAME: AZOG,Inc. One-Step Urine Pregnancy Test (Device or Cassette).

APPLICANT NAME: AZOG, Inc.
1011 US HWY 22 WEST
PHILLIPSBURG, NJ 08865

CONTACT: AZUBUIKE OGALA
Tel.: (908) 213-2900
Fax: (908) 213-2901

INTENDED USE:

The *AZOG* hCG One-Step (Urine) Pregnancy Test (Device or Cassette) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

DESCRIPTION OF THE DEVICE

The *AZOG* hCG One-Step Pregnancy Test (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by adding urine into the sample well of the device and observing 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 to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

DATA TO SUPPORT SUBSTANTIAL EQUIVALENCE:

Assay Precision/Tolerance

An evaluation of AZOG, Inc. hCG One-Step Urine Pregnancy Test (Device or Cassette) was conducted using a panel of 3 coded specimens. The proficiency panel contained negative, low positive and high positive specimens. Two different operators tested each level in replicates of five over a period of three days.
No differences were observed within run (5 replicates), between runs (three different assay days), or between operators (two operators).

Correlation

A total of 150 urine specimens were tested using the AZOG, Inc. hCG One-StepUrine Pregnancy Test (Device or Cassette). When these results were compared to results obtained from a similar device, the result demonstrated 100% overall agreement (for an accuracy of greater than or equal to 99%) of the AZOG, Inc. hCG One-Step Urine Pregnancy Test (Device or Cassette).

Sensitivity and Specificity

The AZOG, Inc. hCG One-Step Urine Pregnancy Test (Device or Cassette) detects hCG at 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (1000 mIU/mL), FSH (1000 mIU/mL) and TSH (1000 μIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

Interference Study

None of the potentially interfering substances tested interfered in the AZOG, Inc. hCG One-Step Urine Pregnancy Test (Device or Cassette) assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 2002

Mr. Azubuike Ogala
President/V.P., Research & Development
Azog Incorporated
1011 US HWY 22
Phillipsburg, NJ 08865

Re: k022681
Trade/Device Name: ACG One-Step Urine Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: DHA
Dated: August 1, 2002
Received: August 12, 2002

Dear Mr. Ogala:

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

510(k) Number (if known): K022681

Device Name: hCG ONE-STEP URINE PREGNANCY TEST

Indications For Use:

AZOG, INC. hCG One-Step Urine Pregnancy Test is intended for the qualitative determination of Human Chorionic Gonadotropin (hCG) in Human Urine The test is for professional use only.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022681

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

SK 48