K041748

AUG - 9 2004

510(k) SUMMARY

DEVICE NAME: AZOG,Inc. One-Step Urine Pregnancy Home Test (DipStick, Cassette and Midstream).

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 Home Test (DipStick, Cassette and Midstream) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy at home.

DESCRIPTION OF THE DEVICE

The *AZOG* hCG One-Step Urine Pregnancy Home 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.

SAFETY AND EFFECTIVENESS DATA:

Assay Precision/Tolerance (k022680 and k022681)

An evaluation of AZOG, Inc. hCG One-Step Urine Pregnancy Test (DipStick, Cassette and Midstream) 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 (k022680, k022681 and current submission)

A total of 310 urine specimens were tested using the AZOG, Inc. hCG One-StepUrine Pregnancy Test (DipStick, Cassette and Midstream). When these results were compared to results obtained from a similar device, the result demonstrated overall agreement of greater than or equal to 99% of the AZOG, Inc. hCG One-Step Urine Pregnancy Home Test (DipStick, Cassette and Midstream).

Sensitivity and Specificity (k022680 and k022681)

The AZOG, Inc. hCG One-Step Urine Pregnancy Test (DipStick, Cassette and Midstream) 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 (k022680 and k022681)

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 9 2004

Mr. Azubuike Ogala
President/V.P., Research & Development
Azog, Inc.
1011 US Hwy 22 West
Phillipsburg, NJ 08865

Re: k041748
Trade/Device Name: AZOG, Inc. hCG One-Step Urine Home Pregnancy Test (Dipstick, Cassette and Midstream)
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: June 18, 2004
Received: June 29, 2004

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 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 will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k041748

Device Name: AZOG, Inc. hCG One-Step Urine Home Pregnancy Test (Dipstick, Cassette and Midstream)

Indications For Use: AZOG, Inc. hCG One-Step Urine Home Pregnancy Test (DipStick, Cassette and Midstream) are intended for the qualitative determination of Human Chrionic Gonadotropin (hCG) in Human Urine. The test is for Over-The-Counter and/or Professional Use. The test is for the early detection of pregnancy.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___x____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041748