# 510 (K) SUMMARY

Date of Summary: April 17, 2003

**Product Name:**

One-Step Pregnancy Test

**Sponsor:**

**Amerisource Pharmacal, Inc.**
**8306 Wilshire Blvd. #774**
**Beverly Hills, CA 90211**

**Correspondent:**

MDC Associates
Fran White
Regulatory Consultant
163 Cabot Street
Beverly, MA 01915

**Substantially Equivalent Devices:**

**Product: Wh Accutest Pregnancy Test**
**Manufactured by: W.H.P.M., Inc.**

**PRODUCT DESCRIPTION:**

The One-Step Pregnancy Test is to be used for detecting human Chorionic Gonadotropin (hCG) in urine. The presence of hCG usually appears about the seventh day after fertilization. The One-Step Pregnancy Test will detect hCG in urine at a concentration level of 25 mIU/ml. The One-Step Pregnancy Test will be sold for under private label in the Over-the-Counter Market.

**INTENDED USE:**

The One-Step Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine. for the early detection of pregnancy. For Over-The-Counter Use.

**SUMMARY OF TECHNOLOGY:**

The One-Step Pregnancy Test employs a unique combination of monoclonal-dye conjugate and polyclonal-solid phase antibodies to selectively identify human Chorionic Gonadotropin (hCG) in urine. As the urine sample flows through the absorbent portion of the device, the antibody-dye conjugate binds to the hCG forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produces a pink-rose color band if hCG concentration is equal to or greater than 25 mIU/ml. In the absence of hCG, there is no line in the reaction zone. Unbound conjugate binds to the reagents in the control zone, producing a pink-rose color band, demonstrating that the reagents are functioning correctly.

**PERFORMANCE DATA:**

A clinical trial was done to compare the performance of the One-Step Pregnancy Test to a FDA cleared product. These data clearly demonstrate the performance of the One-Step Pregnancy Test by Amerisource is substantially equivalent to a commercially available FDA cleared pregnancy test: Stanbio True 20 One-Step Pregnancy Test

| | |
|---|---|
| Sensitivity = | 100% |
| Specificity = | 100% |
| Agreement = | 100% |

**STATEMENT OF SAFETY AND EFFICACY:**

The One-Step Pregnancy Test when compared with another commonly used pregnancy test (Stanbio True) demonstrated 100% performance.

All pregnancy results were confirmed by physical examination and/or ultrasound.

These data clearly demonstrate the safety and efficacy of the One-Step Pregnancy Test and further confirm that the accuracy, sensitivity and specificity of this product when compared to a substantially equivalent device currently being sold.

Testing by untrained women of childbearing years confirmed that the test can be effectively performed by untrained individuals.

**Amerisource Inc. confirms that any/all data provided in this submission may be released upon request.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 17 2003

Amerisource Pharmacal, Inc.
c/o Ms. Fran White
Regulatory Consultant
MDC ASSOCIATES
163 Cabot Street
Beverly, MA 01915

Re: k031271
Trade/Device Name: One-Step Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: April 17, 2003
Received: May 12, 2003

Dear Ms. White:

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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

**510(k) Number:** (if known) K031271
**Device Name:** One-Step Pregnancy Test

**Indication for Use:**

The One-Step Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine, for the early detection of pregnancy. For Over-The -Counter Use.

(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)**

Susan Cooper
**Division Sign-Off**

**Office of In Vitro Diagnostic Device Evaluation and Safety**

**510(k)** K031271