NOV - 8 1999

K993141

510 (k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

Identification: At Home QuickCup Pregnancy Test (Model 9015)

Description: Immunoassay for the qualitative detection of hCG in urine

Name Of Manufacturer: Phamatech
9265 Activity Road #112
San Diego, California 92126, USA

Intended Use: The At Home™ QuickCup Pregnancy Test is intended to detect the presence of Human Chorionic Gonadotropin (hCG) in Urine for the women who suspect they may be pregnant. HCG is a well known and established analyte used to confirm pregnancy because of its early appearance in urine following conception followed by a dramatic increase in concentration.

Technology: The At Home™ QuickCup Pregnancy Test, like many commercially available pregnancy test kits, qualitatively measures the presence of HCG by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the Unipath Clearview HCG (Mountainview, CA 94043), Abbott Laboratories' Fact Plus (Abbott Park, IL 60064) and the Syntron Bioresearch Be Sure Pregnancy Test (Vista, CA 92083). All of the above devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / HCG / antibody / complexes.

Performance: The product performance characteristics of the At Home™ QuickCup Pregnancy Test were evaluated in a clinical sample correlation study and a blind labeled spiked HCG study. The results of these studies demonstrate the Phamatech At Home™ QuickCup Pregnancy Test to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of early pregnancy. Correlations studies, using clinical specimens, produced a >99% correlation when compared to the Quidel Rapidvue (San Diego, CA 92121) and the Syntron Bioresearch Be Sure Pregnancy Test (Vista, CA 92083).

A blind labeled spiked consumer study was performed, the Phamatech At Home™ QuickCup Pregnancy Test exhibited excellent accuracy (exceeding 99%) in the hands of lay users.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech At Home™ Pregnancy Test is substantially equivalent to a variety of pregnancy tests currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 8 1999

Mr. Carl A. Mongiovi
Vice President of Operations
Phamatech
9265 Activity Road
Suite 112
San Diego, California 92126

Re: K993141
Trade Name: At Home™ QuickCup Pregnancy Test
Regulatory Class: II
Product Code: LCX
Dated: September 9, 1999
Received: September 21, 1999

Dear Mr. Mongiovi:

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 (Premarket 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 premarket 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 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

Applicant: Phamatech

510 (k) Number (if known): K 993141 .

Device Name: At Home™ QuickCup Pregnancy Test

Indications for Use:

Over the Counter hCG Pregnancy tests are for those individuals who, for any reason, believe they may be pregnant. This test detects hCG in urine. HCG is a hormone produced by the placenta shortly after implantation. Since hCG is present in the urine of a pregnant woman, it is an excellent marker for confirming pregnancy. Early identification is important in the management of pregnancy. This condition must be identified so that fetal exposure to potentially harmful circumstance may be minimized or eliminated. Many individuals hesitate to seek clinical confirmation of this condition (pregnancy) due to medical examination costs and appointment scheduling difficulties. This device offers an alternative to the initial office visit and will allow for more rapid initiation of pre-natal care upon confirmation testing by trained clinical technicians.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993141

PLEASE DO NOT WRITE BELOW THIS LINE

Concurrence of the CDRH Office of Device Evaluation (ODE)

Division Sign-off
Division of Clinical Laboratory Devices
510 (k) Number:

Prescription Use:_____ OR Over the Counter: ✓
Per 21 CFR 801.109