DEC 30 1999

K994234

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

Identification: At Home Drug Test (Model 9083)

Description: Immunoassay for the qualitative detection of Opiates in urine

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

Intended Use: The At Home Drug Test is a rapid, qualitative immunoassay for the detection of the target drugs/drug metabolites in urine. The cut-off concentration for this test is as follows: Opiates;(2000 ng/ml). This assay is intended for use in the home to assist in the prevention of drug abuse. This kit is designed to incorporate a mechanism for anonymous confirmation testing to be performed at a certified laboratory.

Technology: The At Home Drug Test, like many commercially available drug screening test kits, qualitatively measures the presence of target drugs or their metabolites by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the QuickScreen At Home Drug Test and the Applied Biotech SureStep Test (San Diego, CA 92121). All of the above devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / target drug / antibody / complexes.

Performance: The product performance characteristics of the At Home Drug Test were evaluated in a clinical sample correlation study and a blind labeled spiked study. The results of these studies demonstrate the Phamatech At Home Drug Test to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of the stated target drugs in urine. Correlations studies, using clinical specimens, produced a >98% correlation when compared to the Behring EMIT II (Cupertino, CA 95014) and GC/MS methodology. Clinical studies, performed at two independent laboratories, were also performed. In them the Phamatech QuickScreen™ exhibited excellent overall accuracy (>97%) in the hands of professional users. A comsumer study was also performed. The At Home Drug Test exhibited excellent overall accuracy (4557/4715 correct or 96.65%) in the hands of lay users. Consumer interpretation of the Opiates test in this study showed accuracy to be 918/943 or 97.3%.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech At Home Drug Test Model 9083 is substantially equivalent to a variety of detection tests currently in commercial distribution and is safe in the hands of the lay user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 30 1999

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

Re: K994234
Trade Name: At Home Drug Test (Model 9083)
Regulatory Class: II
Product Code: DJG
Dated: December 14, 1999
Received: December 16, 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): K994234

Device Name: At Home Drug Test (Model 9083)

Indications for Use:

A home drug screening, and if needed, confirmation service. This kit provides a preliminary result for the detection/presence of the following drugs of abuse in urine: Opiates

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K994234

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