K972014

AUG 20

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

Identification: QuickScreen™ One Step Opiate Screening Test (9080)

Description: Immunoassay for the Qualitative Detection of Opiates in Urine

Name Of Manufacturer:

Phamatech
9265 Activity Road #112 / 113
San Diego, California 92126, USA

Intended Use: A drug of abuse assay intended for use in clinical toxicology laboratories, physicians' offices, drug-of-abuse clinics and law enforcement agencies is an in-vitro diagnostic test for the qualitative identification of any addictive narcotic pain relieving opiate drugs, in urine. An opiate is any natural or synthetic drug that has morphine-like pharmacological actions. Measurements that are obtained by this device are used in the diagnosis and treatment of Opiates use or overdose

Technology: The QuickScreen™ One Step Opiates Test utilizes colloidal gold as the label like other commercially available immunoassays for drug of abuse (Opiates) test kits, to qualitatively measure the presence of opiates by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the ABI SureStep (San Diego, CA 92121)and the Syntron Bioresearch Opiates Test (Vista, CA 92083). All of the above devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / Opiates / antibody / complexes.

Performance: The product performance characteristics of the QuickScreen™ One Step Opiates Test was evaluated in a clinical sample correlation study and a blind labeled Opiates study. The results of these studies demonstrate the Phamatech QuickScreen™ One Step Opiates Test to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of Opiates in urine. Correlation studies, using clinical specimens, produced a sensitivity of >95%, specificity of >99% and accuracy >97% when compared to the Syva EMIT II (San Jose, CA 95161) . Two clinical laboratory studies were performed, the Phamatech QuickScreen™ exhibited excellent sensitivity (116/116), specificity (35/35), and accuracy (151/151) versus the EMIT II immunoassay in the hands of professional laboratory technicians.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech QuickScreen™ One Step Opiates ScreeningTest is substantially equivalent to a variety of qualitative Opiates tests currently in commercial distribution.

510(k) SUMMARY
As Required By Section 807.92(c)

QuickScreen™ Opiate Screening Test

Immunoassay for the Qualitative Detection of Opiate and its metabolites in Urine

Name of Product:	QuickScreen™ One Step Opiate Screening Test
Name Of Packager:	Phamatech 9265 Activity Road #112 San Diego, California 92126 USA
Name Of Manufacturer:	Phamatech 9265 Activity Road #108 San Diego, California 92126 USA
Site of Control Testing:	Phamatech 9265 Activity Road #112 San Diego, California 92126 USA
Sites of Clinical Testing:	Poison Laboratories 7272 Clairemont Mesa Blvd. San Diego, CA 92111 Quest Diagnostics Incorporated 7470 Mission Valley Road San Diego, CA 92108

Regulatory Control Number: 012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 20 1997

Mr. Carl A. Mongiovi
Director of Operations
Phamatech
9265 Activity Roads
Suite 112-113
San Diego, California 92126

Re: K972619
Trade Name: QuickScreen™ One Step Opiate Screening Test
Regulatory Class: II Product Code: DJG
II DJJ
Dated: July 8, 1997
Received: July 11, 1997

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 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 requirement, 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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): K972619

Device Name: QuickScreen ™ One Step Opiate Screening Test

Indications for Use:

A drug of abuse assay intended for use in clinical toxicology laboratories, physicians' offices, drug-of-abuse clinics and law enforcement agencies is an in-vitro diagnostic test for the qualitative identification of any addictive narcotic pain relieving opiate drug, in urine. An opiate is any natural or synthetic drug that has morphine-like pharmaco-logical actions. The opiates include drugs such as morphine, heroin, codeine, nalorphine,meperidine and morphine glucuronide. Measurements that are obtained by this device are used in the diagnosis and treatment of opiate use or overdose and in monitoring the levels of opiate administration to ensure appropriate therapy.

PLEASE DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH Office of Device Evaluation (ODE)

Veronica J. Calvin for C. Montgomery
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972619

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

Prescription Use: ✓ OR Over the Counter_____

Rx/AOC