FEB 5 1999

K982938

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

Identification:	QuickScreen™ Methadone Screening Test
Description:	Immunoassay for the qualitative detection of methadone in urine
Date Prepared:	25 January 1999
Name Of Manufacturer:	Phamatech 9265 Activity Road #112 San Diego, California 92126, USA
Contact Person(s):	Carl Mongiovi, Director of Operations, and Roland Strickland, Quality Assurance Manager

Intended Use: The QuickScreen™ Methadone Screening Test is a rapid, qualitative immunoassay used to screen for the detection of methadone in urine at a cutoff concentration of 300 ng/mL. This assay is intended for professional use to assist in preventing drug abuse.

This test provides only a preliminary test result. A more specific alternate test method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result.

Technology: The QuickScreen™ 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 ABMC (Ancramdale, NY) and the Applied Biotech SureStep Test (San Diego, CA 92121). All of the above devices rely on the basic immunochemical assay principle of recognition and formation of specific antibody / target drug complexes.

Performance: The product performance characteristics of the QuickScreen™ Methadone Screening Test were evaluated in a clinical sample kit comparison study, using 49 methadone-positive urine specimens and 60 methadone-negative urine specimens, and in blind-labeled spiked studies. The results of these studies demonstrate the Phamatech QuickScreen™ 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.

In-house Kit Comparison studies, using clinical specimens, correctly identified 49 of 49 methadone-positive urine specimens and 60 of 60 methadone-negative urine specimens, producing a >99% agreement with the Behring EMIT II (Cupertino, CA 95014) and GC/MS methodologies.

Clinical specimen testing, using the same set of clinical urine specimens, was also performed at two independent laboratories. During clinical specimen testing, the Phamatech QuickScreen™ exhibited excellent overall agreement (>98%) in the hands of professional users by correctly identifying 47 of 49 methadone-positive urine specimens and 60 of 60 methadone-negative urine specimens. Two (2) samples at 324 and 336 ng/mL (8% and 12% above cutoff, respectively) gave negative results with QuickScreen.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech QuickScreen™ Methadone Screening Test is substantially equivalent to a variety of detection tests currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 5 1999

Mr. Carl Mongiovi
Director of Operations, and
Roland Strickland,
Quality Assurance
Phamatech
9265 Activity Road #112
San Diego, California 92126

Re: K982938
Trade Name: QuickScreen Methadone Screening Test
Regulatory Class: II
Product Code: DJR
Dated: December 23, 1998
Received: December 29, 1998

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 982938

Device Name: QuickScreen™ Methadone Screening Test

Indications for Use:

An in vitro diagnostic test for the qualitative identification of methadone in urine. This test was calibrated against methadone at a cut-off concentration of 300 ng/ml. Measurements obtained by this device are used in screening for drug abuse.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 98 2938

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