K982152

SEP 21 1998

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

Identification: QuickScreen™ Barbiturates Screening Test (9020/9021)

Description: Immunoassay for the qualitative detection of barbiturates in urine

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

Intended Use: The QuickScreen™ Barbiturates Screening Test is a rapid, qualitative immunoassay for the detection of barbiturates compounds in urine at a cutoff concentration of 200 ng/mL of Secobarbital. This assay is intended for professional use.

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 chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

Barbiturates form a large class of abused pharmaceuticals. These products are anxiolytics, sedatives/hypnotics, anticonvulsants and anesthetic drugs. As CNS depressants, the barbiturates exert effects on excitatory and inhibitory synaptic neurotransmission. The ultra short acting barbiturates used for anesthesia, such as Thiopental, depress excitatory neuronal transmission to a greater extent than the anticonvulsant barbiturates such as Pentobarbital. Barbiturates are rapidly and completely absorbed with nearly 100% bioavailability. Short-acting barbiturates are generally excreted in urine as metabolites, while long-acting barbiturates are primarily excreted unchanged. Ratios of drugs to metabolites vary, dependent upon duration of action.

Technology: The QuickScreen™ Test, like many commercially available drug screening test kits, qualitatively measures the presence of barbiturates by visual, color sandwich, one-step immunoassay technology. Examples of such predicate devices include the ABMC Rapid Drug Screen (Ancramdale, NY) 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 / barbiturates / antibody complexes.

Performance: The product performance characteristics of the QuickScreen™ Barbiturates Screening Test were evaluated in a clinical sample correlation study and a blind-labeled spiked sample study. 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 barbiturates in urine. Correlation studies, using clinical specimens, produced a 97% agreement when compared to the Behring EMIT II (Cupertino, CA 95014).

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 21 1998

Carl Mongiovi
Director of Operations
Phamatech
9265 Activity Road #112-113
San Diego, California 92126

Re: K982152
QuickScreen Barbiturates Screening Test
Regulatory Class: II
Product Code: DIS
Dated: August 14, 1998
Received: August 18, 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 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/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): **K982152**

Device Name: **QuickScreen™ Barbiturates Screening Test**

Indications for Use:

An in vitro test for the qualitative identification of barbiturates in urine at a cutoff concentration of 200 ng/mL of Secobarbital. Measurements that are obtained by this device are used in the screening for drug abuse.

PLEASE DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number _____

Division Sign-Off
Division of Clinical Laboratory Devices

510(k) Number: K982152

Prescription Use: ✓ OR Over the Counter: _____

Per 21 CFR 801.109