JUL 2 0 2001

K012107

510k Submission for

LiveSure™ PHENECYCLINE (PCP) SCREEN TESTS

Pan Probe Biotech, Inc.

Revision E, July 16, 2001

SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS

The sponsor, Pan Probe Biotech, Inc., has developed, manufactured, and tested under Good Laboratory Practices guidelines, in vitro diagnostic (IVD) devices for qualitative testing of urine samples for the presence of Phencyclidine, analogs, and metabolites in an IVD screening format.

The trade names for the devices are the Pan Probe Biotech LiveSure™ Phencyclidine Screen Test Card and Test Strip, having a FDA designated name of Phencyclidine Test Systems. These Class II devices, as yet, do not have a 21 CFR 862 classification, but do have a product code: LCM. These IVD devices are intended for medical or forensic screening of urine for Phencyclidine.

The Pan Probe Biotech LiveSure™ Phencyclidine Screen Test Card and Test Strip (i.e., LiveSure™ Phencyclidine Test) devices are rapid qualitative competitive chromatographic IVD immunoassays, in which a chemically labeled drug conjugate competes with any Phencyclidine (PCP) drug, analogs or metabolites that may be present in test urinary samples for limited specific antibody binding sites. LiveSure™ PCP devices have a unique membrane pre-coated with a gold conjugate immunoassay indicator that is used is pre-labeled with specific monoclonal antibody from mouse directed against PCP. Each Test Strip and Test Card consists of a membrane absorbent pad having a gold-probe-conjugate pre-labeled with specific monoclonal antibody from mouse that is directed against PCP, and a chromatographic membrane pre-coated with a chemically modified PCP-conjugate as a capture reagent. The Test region of each device has been layered with PCP-conjugate as a 1st capture reagent, while the Process Control region has been pre-coated with a 2nd anti-mouse antibody reagent derived from goat. A pink colored anti-PCP monoclonal antibody-colloidal gold conjugate pad is placed to the right of the test strip. In the absence of PCP drug, analogs or metabolites in any urine sample, the pink colored antibody-colloidal gold conjugate moves chromatographically along with the urinary sample on the membrane by capillary action. Antibody-colloidal gold conjugate binds to PCP-drug conjugate, forming an antibody-antigen complex. This antibody-PCP-drug conjugate appears as second visible pink colored band and captured reagent at the test region. Any PCP drug, analogs or metabolites that are present in sample urine act as antigens, competing with PCP-drug conjugate at the test band region for limited PCP-antibody binding sites on antibody-colloidal gold conjugate. When a sufficient concentration of urinary PCP drug, analogs or metabolites are present, these analytes block the limited antibody binding sites. This blockage-binding prevents attachment of pink colored antibody-colloidal gold conjugate to the PCP-drug conjugate zone located at the test band region. To serve as a procedural control, a pink colored band in a control region will always appear regardless of the presence of PCP in urinary samples. Thus, negative urine samples produce two pink colored bands, while positive urine samples produce only one pink colored band.

In-house testing of LiveSure™ Phencyclidine Screen Test Card and Test Strip devices against EMIT® II Assay as a predicate device provided data essentially showing equivalency between these devices and the predicate EMIT® II Assay. Additionally, independent clinical testing of 297 urine samples against LiveSure™ Phencyclidine Screen Test Card and Test Strip devices, as well as EMIT® II Assay at an external reference laboratory resulted in a 100% percent agreement with all GC/MS quantitative positive results. Moreover, LiveSure™ Phencyclidine Test Card and Test Strip gave 97.2% of both agreement with GC/MS negative results, whereas EMIT II® yielded a 98.1% correlation with GC/MS negatives. In comparing the Test Card and Test Strip positives with EMIT® II positives, 100% agreement with EMIT® II was found, respectively. Specificity of Test Card and Test Strip negatives with EMIT® II negatives was shown to be 99.0%, respectively. Finally, the LiveSure™ Phencyclidine Test Card and the Test Strip gave overall accuracy results of 291/297 (98.0%), versus GC/MS data, whereas 295/297 (99.3%) accuracy was obtained with EMIT®II, respectively. Thus, as judged against GC/MS results from an independent laboratory, the LiveSure™ Phencyclidine Test Card and Test Strip were determined to be equivalent in performance to each other and similarity in capability versus assays with EMIT®II Phencyclidine Assay.

Additional information on this submission may be obtained by contacting Alice Yu, Vice President, Pan Probe Biotech, Inc. at: 1-858-689-9936 or by fax at 1-858-689-6896.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 0 2001

Pan Probe Biotech, Inc.
c/o James M. Barquest, Ph.D.
California Department of Health Services
Food and Drug Branch
PO Box 942732
601 North Seventh Street (MS 357)
Sacramento, CA 94234-7320

Re: 510(k) Number: K012107
Trade/Device Name: Pan Probe Biotech LiveSure™ Phencyclidine (PCP) Screen Tests
Regulatory Class: II
Product Code: LCM
Dated: July 3, 2001
Received: July 5, 2001

Dear Dr.Barquest:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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" (21CFR 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

510(k) Number (if known): Not yet assigned

Device Name: Pan Probe Biotech LiveSure™ Phencyclidine (PCP) Screen Tests

INDICATIONS FOR USE STATEMENT:

The Pan Probe Biotech LiveSure™ Phencyclidine Screen Test Card and Test Strip devices are rapid *in vitro* diagnostic (IVD) qualitative lateral flow immuno-chromatographic competitive urinary assays for detection of Phencyclidine, analogs and metabolites (collectively: PCP) in human urine at the NIDA (National Institute on Drug Abuse) and SAMHSA (Substance Abuse and Mental Health Services Administration) cut-off level of 25 ng PCP/ml. These IVD tests are intended for visual, qualitative screening, for professional use only, and are not intended for quantitative results, nor for over the counter sales. Pan Probe LiveSure™ PCP Screen Tests for PCP provide only preliminary qualitative analytical data. A more specific quantitative alternative method must be used in order to obtain a confirmed analytical result. NIDA and SAMHSA have established gas chromatographic/mass spectrometry (GC/MS) as the preferred confirmatory method. Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012107

Prescription Use: ✓ **or** **Over-the-Counter Use:** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**