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510k Submission for

LiveSure™ BARBITURATES SCREEN TESTS

K012133

Pan Probe Biotech, Inc.

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 Barbiturates, analogs, and metabolites in a IVD screening format.

The trade name of the devices are the Pan Probe Biotech LiveSure™ Barbiturates Screen Test Card and Test Strip, having a FDA designated common name of Barbiturates Test Systems, and a classification as a Class II device per 21 CFR 862.3150, with product code: DIS. These IVD devices are intended for medical and forensic screening of urines for Barbiturates, analogs and metabolites.

The Pan Probe Biotech LiveSure™ Barbiturates Screen Test Card and Test Strips (i.e., LiveSure™ Barbiturates) devices are rapid qualitative competitive chromatographic IVD immunoassays, in which chemically labeled drug conjugate competes with any Barbiturate (BAR) drugs, analogs or metabolites that may be present in test urinary samples for limited specific antibody binding sites. LiveSure™ Barbiturates 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 BAR. 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 BAR, and a chromatographic membrane pre-coated with a chemically modified Barbiturate [Secobarbital] drug-conjugate as a capture reagent. The Test region of each device has been layered with a Barbiturate [Secobarbital] drug-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-BAR monoclonal antibody-colloidal gold conjugate pad is placed to the right of a test strip. In the absence of BAR drugs, analogs or metabolites in urine, pink colored antibody-colloidal gold conjugates move chromatographically along with a urinary sample on the membrane by capillary action. Antibody-colloidal gold conjugate binds to BAR-drug conjugate, forming an antibody-antigen complex. This antibody-BAR-drug conjugate appears as a second visible pink colored band and as a captured reagent at the test region. Any BAR drugs, analogs or metabolites that are present in a sample urine act as antigens, competing with BAR-drug conjugate at the test band region for limited BAR-antibody binding sites on antibody-colloidal gold conjugate. When a sufficient concentration of urinary BAR drugs, 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 at the BAR-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 presence of BAR in urine samples. Thus, negative urine samples produces two pink colored bands, while positive urine samples produce only one pink colored band.

In-house testing of LiveSure™ Barbiturates Screen Test Card and Test Strip devices against EMIT® II Assay as a predicate has provided data essentially showing equivalency between these devices and the predicate EMIT® II Assay. Additionally, independent clinical testing of 335 urine samples against LiveSure™ Barbiturates Screen Test Card and Test Strip devices, as well as EMIT® II Assay at an external reference laboratory has resulted in a 100% percent agreement with all GC/MS quantitative positive results. Moreover, LiveSure™ Barbiturates Test Card or Strip gave a 100% and a 99.6% agreement with GC/MS negative results. In comparing both the Test Card positives and Test Strip positives with the EMIT® II positives, a 100% agreement with EMIT® II was obtained with both Test devices. Specificity of the Test Card and Test Strip negatives with EMIT® II negatives was shown to be a 100% and a 99.6%, respectively. In terms of overall accuracy of values at and below the ±25% range of the NIDA/SAMHSA cut-off of 300 ng BAR/ml, however, the LiveSure™ Barbiturates Screen Test Card and Strip yielded no false positives or FP. Finally, versus GC/MS quantitative BAR data, the LiveSure™ Barbiturates Test Card and Test Strip gave overall accuracy results of 335/335 (100%) and 334/335 (99.7%), respectively, whereas 335/335 (100%) and 334/335 (99.7%) accuracy was obtained with EMIT®II. Thus, as judged against GC/MS results from an independent laboratory, the LiveSure™ Barbiturates Test Card and Test Strip were determined to be equivalent in performance with each other, and with EMIT®II assays.

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

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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: K012133
Trade/Device Name: Pan Probe Biotech LiveSure™ Barbiturates Screen Tests
Regulation Number: 862.3150
Regulatory Class: II
Product Code: DIS
Dated: July 3, 2001
Received: July 9, 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™ Barbiturates Screen Tests

INDICATIONS FOR USE STATEMENT:

The Pan Probe Biotech LiveSure™ Barbiturates Screen Test Card and Test Strip devices are rapid *in vitro* diagnostic (IVD) qualitative lateral flow immuno-chromatographic competitive urinary assays for detection of Barbiturate drugs (e.g., Secobarbital, Pentabarbital, Phenobarbital, etc.), analogs and metabolites (collectively termed: BAR) in human urine at the NIDA (National Institute on Drug Abuse) and SAMHSA (Substance Abuse and Mental Health Services Administration) cut-off level of 300 ng BAR/ml. The cut-off for both LiveSure™ Test Card and Test Strip device methods has been set at 300 ng BAR drug/ml based upon calibration using Secobarbital as a prototype Barbiturate/BAR drug, and using Secobarbital standards with a GC/MS method for the quantitation of all the Secobarbital standard and urine test solutions. 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 Biotech LiveSure™ BAR Screen Tests for BAR provide only preliminary analytical data. A more specific quantitative alternative method must be used in order to obtain a confirmed analytical result. Both NIDA and SAMHSA have established gas chromatography/mass spectrometry (GC/MS) as a 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012133

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