K012131

JUL 2 0 2001

510k Submission for

LiveSure™ BENZODIAZEPINES 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 Benzodiazepines, analogs, and metabolites in an IVD screening format.

The trade name of the devices are the Pan Probe Biotech LiveSure™ Benzodiazepines Screen Test Card and Test Strip, having a FDA designated name of Benzodiazepines Test Systems, and a classification as a Class II device per 21 CFR 862.3170, with product code: JXM. These IVD devices are intended for medical/forensic screening of urines for Benzodiazepines, analogs, and metabolites.

The Pan Probe Biotech LiveSure™ Benzodiazepines Screen Test Card and Test Strip (i.e., LiveSure™ Benzodiazepines) devices are rapid qualitative competitive chromatographic IVD immunoassays, in which chemically labeled drug conjugate competes with any Benzodiazepine (BZD) drugs, analogs or metabolites that may be present in test urine samples for limited specific antibody binding sites. LiveSure™ Benzodiazepines 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 BZD drugs. 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 BZD drugs, and a chromatographic membrane pre-coated with a chemically modified Benzodiazepine [Oxazepam] drug-conjugate as a capture reagent. The Test region of each device has been layered with a Benzodiazepine [Oxazepam] 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-BZD monoclonal antibody-colloidal gold conjugate pad is placed to the right of a test strip. In the absence of BZD drugs, analogs or metabolites in urine, pink colored antibody-colloidal gold conjugates move chromatographically along with the urinary samples on the membrane by capillary action. Antibody-colloidal gold conjugate binds to BZD-drug conjugate, forming an antibody-antigen complex. This antibody-BZD-drug conjugate appears as second visible pink colored band and captured reagent at the test region. Any BZD drugs, analogs or metabolites that are present in a sample urine act as antigens, competing with BZD-drug conjugate at the test band region for limited BZD-antibody binding sites on antibody-colloidal gold conjugate. When a sufficient concentration of urinary BZD 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 BZD-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 BZD 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™ Benzodiazepines 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 387 urine samples against LiveSure™ Benzodiazepines 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™ Benzodiazepines Test Card or Strip gave both 99.3% agreement with GC/MS negative results. In comparing the Test Card and Test Strip positives with EMIT® II positives, both 98.3% respective agreement with EMIT® II was found. Specificity of Test Card and Test Strip negatives with EMIT® II negatives was shown to be 99.5%, respectively. In terms of overall accuracy of values at and below the ±25% range of the NIDA/SAMHSA cut-off of 300 ng/ml of Benzodiazepines, however, the LiveSure™ Benzodiazepines Screen Test Card and Strip yielded no false positives or no FP, but EMIT®II resulted in 1 FP values for urine samples with GC/MS results below ng/ml. Finally, the LiveSure™ Benzodiazepines Test Card and the Test Strip gave overall accuracy results of 385/387(99.5%) for both, versus GC/MS data, whereas 385/387(99.5%) accuracy was obtained with EMIT®II. Thus, as judged against GC/MS results from an independent laboratory, the LiveSure™ Benzodiazepines Test Card and Test Strip were determined to be equivalent in performance to each other and somewhat superior in capability versus assays with EMIT®II.

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: K012131
Trade/Device Name: Pan Probe Biotech LiveSure™ Benzodiazepines Screen Tests
Regulation Number: 862.3170
Regulatory Class: II
Product Code: JXM
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™ Benzodiazepines Screen Tests

INDICATIONS FOR USE STATEMENT:

The Pan Probe Biotech LiveSure™ Benzodiazepines Screen Test Card and Test Strip devices are rapid *in vitro* diagnostic (IVD) qualitative lateral flow immuno-chromatographic competitive urinary assays for detection of Benzodiazepines drugs, analogs and metabolites (BZD) 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 BZD/ml. The cut-off for both LiveSure™ Test Card and Test Strip device methods has been set at 300 ng BZD drug/ml based upon calibration using Oxazepam as a prototype Benzodiazepine/BZD drug, and using Oxazepam standards with a GC/MS method for the quantitation of all the Oxazepam 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™ BZD Screen Tests for BZD 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

n Sign-Off)
Clinical Laboratory Devices
K012131

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