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

The Assigned 510(k) number is k080467 NOV 2 5 2008

Date of Summary: November 21, 2008

Common Name: Drugs of Abuse Screening Tests

Regulatory Information:

1. Regulation sections: 21 CFR part 862.3870 (THC), 3250 (COC), 3640 (MOR), 3100 (AMP), 3610 (MET), 3150 (BAR), 3170 (BZO), 3620 (MTD), 3910 (NOR), 3610 (MDMA), 3620 (EDDP), 3650 (BUP), 3640 (MOR300), and Non-applicable (PCP).
2. Classification: Class II:
3. Product Code: LDJ (THC), DIO (COC), DNK (MOR), DKZ (AMP), DJC (MET), DIS (BAR), JXM (BZO), DJR (MTD), LFG (NOR), DJC (MDMA), DJR (EDDP), DJG (BUP), DNK (MOR300), and LCM (PCP).
4. Panel: Clinical Toxicology, 91

Name of Submitter:
Applied DNA Technologies Inc.
10239 Flanders Court
San Diego, CA 92121

Contact Person:
Feng-Yu Lee

Identification / Product Name:
Bionexia™ Single and Multi-Strip Cassette/Dipstick DOA Screen Panels

Description:
One-step, colloidal gold based chromatographic immunoassay for the rapid, qualitative detection of Marijuana, Cocaine, Phencyclidine, Morphine, Methamphetamine, Methadone, Amphetamine, Barbiturates, Benzodiazepines, Nortriptyline, Ecstasy, Buprenorphine and Methadone metabolite – EDDP, in human urine.

Intended Use:
The Applied DNA Technologies Bionexia™ DOA Screen Panels are rapid chromatographic immunoassays for the qualitative and simultaneous detection of one to thirteen of the following drugs in a variety of combinations in human urine. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

Analyte	Abbreviation	Direct Calibrator	Cutoff Concentration
Amphetamine	**AMP**	**Amphetamine**	**1000 ng/ml**
Barbiturate	**BAR**	**Secobarbital**	**300 ng/ml**
Benzodiazepines	**BZO**	**Oxazepam**	**300 ng/ml**
Cocaine	**COC**	**Benzoylecgonine**	**300 ng/ml**
Marijuana	**THC**	**11-nor-Δ^9-THC9-COOH**	**50 ng/ml**

Methamphetamine	**MET**	**Methamphetamine**	**1000 ng/ml**
Methadone	**MTD**	**Methadone**	**300 ng/ml**
Morphine	**MOR**	**Morphine**	**2000 ng/ml**
Morphine	**MOR**	**Morphine**	**300 ng/ml**
Phencyclidine	**PCP**	**Phencyclidine**	**25 ng/ml**
Nortriptyline	**NOR**	**Nortriptyline**	**1000 ng/ml**
Ecstasy	**MDMA**	**3,4-Methylenediioxy-MET**	**500 ng/ml**
Buprenorphine	**BUP**	**BUP-3-D-Glucuronide**	**10 ng/ml**
EDDP	**EDDP**	**2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine**	**100 ng/ml**

The test kits are for health care professionals use including professionals at point of care sites to assist in the determination of drug compliance.

This assay provided only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Predicate Kit:
ACON One Step Drug Screen Tests are used as predicate device for ADT's Bionexia™ Single and Multi-Strip DOA Screen Panels to compare their performance with the GC/MS confirmed clinical urine specimens.

510(k) numbers for predicate devices are:

ACON One Step Ecstasy Screen Test	K 022589
ACON One Step Morphine 300 Test	K 013380

Performance:
The product performance characteristics of ADT's Bionexia™ DOA Screen Panels were evaluated in the blind-labeled clinical specimen correlation study and in the blind-labeled spiked control studies including point-of-care site study. The results of these studies demonstrate ADT's Bionexia™ DOA Screen Panels to be substantially equivalent to the performance characteristics of GC/MS methodology as well as ACON's One Step DOA Test Panels. Correlation studies, using clinical specimens, produced a > 93.9% total correlation when compared to the GC/MS or LC/MS methodology.

Bionexia™ DOA Screening Panels vs. GC/MS (or LC/MS) Analysis

Samples with drug concentration above the cutoff level were considered presumptive positive and concentration below the cutoff were considered negative.

Table 1. (Previously approved panels)

Test	Positive Agreement	Negative Agreement	Overall Agreement
AMP	46/48 = 95.8%	55/55 = 100%	101/103 = 98.1%
BAR	45/46 = 97.8%	51/52 = 98.1 %	96/98 = 98.0%
BZO	41/43 = 95.3%	52/56 = 92.9%	93/99 = 93.9%
COC	55/56 = 98.2%	53/54 = 98.1%	108/110 = 98.2%
MET	61/63 = 96.8%	52/52 = 100%	113/115 = 98.3%
MOR	40/41 = 97.6%	63/64 = 98.4%	103/105 = 98.1%
MTD	49/51 = 96.1%	54/54 = 100%	103/105 = 98.1%
PCP	45/46 = 97.8%	48/48 = 100%	93/94 = 98.9%
NOR	35/38 = 92.1%	57/57 = 100%	92/95 = 96.8%
THC	60/62 = 96.8%	59/60 = 98.3%	119/122 = 97.5%

Table 2. (Additional Panels)

Drug / Cutoff (ng/ml)	Candidate Device Results	**No Drug present**	**Negative** (Less than 50% the cutoff concentration by GC/MS or LC/MS analysis	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (Greater than 50% above the cutoff concentration)	**% Agreement**
MDMA	+	**0**	**0**	**0**	**12**	**63**	**100.0 %**
500	-	**35**	**7**	**9**	**0**	**0**	**100.0 %**
EDDP	+	**0**	**0**	**0**	**3**	**65**	**98.6%**
100	-	**38**	**0**	**4**	**1**	**0**	**100.0%**
BUP	+	**0**	**0**	**0**	**4**	**72**	**100.0%**
10	-	**35**	**1**	**5**	**0**	**0**	**100.0%**
MOR	+	**0**	**0**	**1**	**11**	**50**	**96.8 %**
300	-	**35**	**0**	**12**	**2**	**0**	**97.9 %**

Conclusion:

Results of Accuracy, Sensitivity, Precision, POC site study, Specificity and Interference studies demonstrate the substantial equivalency between ADT's Bionexia™ DOA Screen Panels and the ACON One Step DOA Screen Test panels. It is also demonstrated that ADT's Bionexia™ DOA Screen Panels are safe and effective in detecting Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methamphetamine, Methadone, Morphine, Phencyclidine, Nortriptyline, Ecstasy, Buprenorphine and Methadone metabolite – EDDP, in human urine specimen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Applied DNA Technologies, Inc.
c/o Ms. Feng-Yu Lee
Vice President of Operation
26251 Verona Place
Mission Viejo, CA 92692

NOV 2 5 2008

Re: k080467
Trade Name: ADT's Bionexia™ Single and Multi-Strip Cassette/Dipstick DOA Screen Panels
Regulation Number: 21 CFR §862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: LDJ, DIO, DNK, DKZ, DJC, DIS, JXM, DJR, LFG, DJC, DJR, DJG, LCM
Dated: November 11, 2008
Received: November 13, 2008

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k080467

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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