



IND Diagnostic, Inc  
c/o Kai Lou  
Regulatory Affairs Department  
1629 Fosters Way  
Delta, British Columbia, Canada V3M 6S7

10903 New Hampshire Avenue  
Silver Spring, MD 20993

JUL 30 2012

Re: k121231  
Trade Name: IND Drug Home Multi-Panel Test (2-5) – Cassette and Strip Formats  
IND Amphetamine Home Test – Cassette and Strip Formats  
IND Methamphetamine Home Test – Cassette and Strip Formats  
IND Cocaine Home Test – Cassette and Strip Formats  
IND Morphine Home Test – Cassette and Strip Formats  
IND Marijuana Home Test – Cassette and Strip Formats  
Regulation Number: 21 CFR §862.3100  
Regulation Name: Amphetamine test system  
Regulatory Class: Class II  
Product Codes: NGT, NFY, NGG, NFW, NGI  
Dated: July 5, 2012  
Received: July 10, 2012

Dear Kai Lou,

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

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 (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

**510(k) Number (if known):**

**Device Name:** IND Drug Home Multi-Panel Test (2-5) – Cassette and Strip Formats  
IND Amphetamine Home Test – Cassette and Strip Formats  
IND Methamphetamine Home Test – Cassette and Strip Formats  
IND Cocaine Home Test – Cassette and Strip Formats  
IND Morphine Home Test – Cassette and Strip Formats  
IND Marijuana Home Test – Cassette and Strip Formats

**Indications for Use:**

The IND Drug Home Test is a rapid chromatographic immunoassay multi-panel or single drug test for the qualitative detection of one or more of the following drugs: Amphetamine, Methamphetamine, Cocaine, Marijuana, and Morphine in human urine. It is intended for over-the-counter use.

<u>Drug Name (Code)</u>	<u>Cut-off</u>
Amphetamine (AMP)	1000 ng/mL
Methamphetamine (MET)	1000 ng/mL
Cocaine (COC)	300 ng/mL
Marijuana (THC)	50 ng/mL
Morphine (MOR)	300 ng/mL

The test is intended for over-the counter (OTC) use as the first step in a two step process to provide consumers with information concerning the presence or absence of the above stated drugs or metabolites in a urine sample. The test provides only preliminary test results. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. GC/MS (Gas Chromatography / Mass Spectrometry) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when the preliminary result is positive.

Information regarding confirmatory testing, the second step in the process, is provided in the package labeling.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   X    
(21 CFR 807 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)



**Division Sign-Off**

**Office of In Vitro Diagnostic  
Device Evaluation and Safety**

510(k)   K121231