TABLE 4 SUMMARY

SEP 19 2011

1. Date the summary was prepared: June 15, 2011

2. Submitter's name:
Address:
Guangzhou Wondfo Biotech Co., Ltd.
South China University of Technology
Guangzhou, P.R. China 510641

Phone: 012-86-20-32296069

Name of contact person:
Joe Shia
LSI International Inc.
504 East Diamond Ave.,
Suite F Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6231

3. Name of the device

Common or usual name: Methylenedioxymethamphetamine Urine Test
Morphine Urine Test

Trade or proprietary name: Wondfo Methylenedioxymethamphetamine Urine Test
Wondfo Morphine Urine test

Classification: All are Class II medical devices with the following various product codes with Code of Federal Regulation references:

Product Code	CFR #
LFG	21CFR 862.3610
DJG	21CFR862.3650

4. The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:
1). Acon Laboratories, Inc., ACON® One Step Drug Screen Test, K020771.
2). Acon Laboratories, Inc., Acon® MDMA One Step Ecstasy Test, K022589

5. Description of the device:
Assay Principle: Immunochromatograph assay for Methylenedioxymethamphetamine and Morphine Urine Test using a lateral flow, one step system for the qualitative detection of MDMA, Morphine (target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate from mouse against drug with gold chloride and fixed drug-protein conjugate and anti-mouse IgG polyclonal antibody in membrane.

6. Intended use of the device:
Wondfo Methylenedioxymethamphetamine Urine Test and Wondfo Morphine Urine are intended for the qualitative determination of MDMA, Morphine (target analyte) at the specific cut-off concentration in human urine. They are intended for healthcare professional use and over the counter use.

7. Comparison to the predicate device
A summary comparison of the features of the Wondfo Methylenedioxymethamphetamine Urine Test and Wondfo Morphine Urine test and the predicate devices is provided in the Table 1.

Table 1: Features comparison of Wondfo assays and the predicate devices

Item	Device	Predicate
Indication(s) for use	For the qualitative determination of Methylenedioxymethamphetamine, Morphine individual in human urine.	Same (but the number of drugs detected different)

Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type Of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Methylenedioxymethamphetamine:500 ng/ml Morphine: 300ng/ml	Same (but the number of drugs detected different)
Configurations	Cup, dip card	Card, dip card with an integrated cup (same) Strip, device for MDMA
Intended Use	OTC Use & Prescription Use	Prescription Use

The Wondfo Methylenedioxymethamphetamine Urine Test and Wondfo Morphine Urine test have similar technological characteristics and performance to the predicate and are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Guangzhou Wondfo Biotech Co., Ltd.
c/o Joe Shia
Regulatory Consultant
LSI International Inc.
12828 Doe Lane
Gaithersburg, MD 20878

SEP 19 2011

Re: k112236
Trade Name: Wondfo Methylenedioxymethamphetamine Urine Test
Wondfo Morphine Urine Test
Regulation Number: 21 CFR 862. 3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Codes: LAF, DJG
Dated: August 1, 2011
Received: August 4, 2011

Dear Mr. Shia:

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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known):_____

Device Name: Wondfo Methylenedioxymethamphetamine Urine Test

Indications for Use:

Wondfo Methylenedioxymethamphetamine Urine Test is an immunochromatographic assay for the qualitative determination of MDMA in human urine at a cutoff concentration of 500ng/mL. The test is available in a dip card format and a cup format. It is intended for prescription use and over the counter use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a conformed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use X **(21 CFR Part 801 Subpart D)** **And/Or** **Over the Counter Use** X **(21 CFR Part 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)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K112236

Indications for Use Form

510(k) Number (If known):_____

Device Name: Wondfo Morphine Urine Test

Indications for Use:

Wondfo Morphine Urine Test is an immunochromatographic assay for the qualitative determination of Morphine in human urine at a cutoff concentration of 300ng/mL. The test is available in a dip card format and a cup format. It is intended for prescription use and over the counter use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a conformed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use _X_ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _X_ (21 CFR Part 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)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112236