TABLE 4

SUMMARY

MAY 2 0 2011

Submitter's name:
Address:

Phone:

Guangzhou Wondfo Biotech Co., Ltd.
South China University of Technology
Guangzhou, P.R. China 510641
012-86-20-32296069

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

Date the summary was prepared: December 13, 2010

Name of the device: Cannabinoids Urine Test
Trade or proprietary name: Cannabinoids Urine Test
Common or usual name: Immunochromatographic test for the qualitative detection of Cannabinoids

Classification: Class II medical device with the product codes with Code of Federal Regulation references:

Product Code	CFR #
LDJ	862.3870

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:
Acon Laboratories, Inc. One Step Drug Screen Test Card, K020771.

Description of the device:

Assay Principle: Immunochromatographic assay for Cannabinoids urine test using a lateral flow system for the qualitative detection of Cannabinoids in human urine. Each assay uses a monoclonal antibody-dye congugate from mouse against drug with gold chloride and fixed drug-protein conjugate and anti-mouse IgG polyclonal antibody in membrane.

Intended use of the device:

The Cannabinoids Urine Test is intended for the qualitative determination of Cannabinoids in human urine. They are intended for healthcare professional use and over the counter use.

Summary of the technological characteristics of our device compared to the predicate device:

The Wondfo Biotech Co., Ltd. Cannabinoids 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

MAY 20 2011

Guangzhou Wondfo Biotech Co., LTD.
c/o Joe Shia, LSI International Inc.
504 East Diamond Ave.
Suite F
Gaithersburg, MD 20877

Re: k110182
Trade Name: Wondfo Cannabinoids Urine Test
Regulation Number: 21 CFR §862.3870
Regulation Name: Cannabinoid Test System
Regulatory Class: Class II
Product Codes: LDJ
Dated: May 16, 2011
Received: May 19, 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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, 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): K110182

Device Name: Wondfo Cannabinoids Urine Test

Indications for Use:

Wondfo Cannabinoids Urine Test is an immunochromatographic assay for the qualitative determination of Cannabinoids in human urine. The test is available in a cassette format and a strip format. The test has a cutoff of 50ng/mL of Cannabinoids. 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	And/Or	Over the Counter Use X
(21 CFR Part 801 Subpart D)		(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) K110182