TAB 4 SUMMARY

Submitter's name: Guangzhou Wondfo Biotech Co., Ltd.

Address: South China University of Technology
Guangzhou, P.R. China 510641

Phone: 012-86-20-871-12194

Name of contact person: Howard Mann
Sherbo Associates
8903 Spruce Mill Drive
Yardley, PA 19067
Phone: (215) 369-3785
Fax: (215) 369-5246

Date the summary was prepared: September 16, 2004
Name of the device: One Step Multiple Drugs of Abuse Assays
Trade or proprietary name: One Step Multiple Drugs of Abuse Assays
Common or usual name: Immunochromatographic test for the qualitative detection of:

- Amphetamine
- Barbiturate
- Benzodiazepine
- Cocaine
- Marijuana
- Methadone
- Methamphetamine
- Methylenedioxymethamphetamine
- Morphine
- Opiate
- Phencyclidine
- Tricyclic antidepressant drugs

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

Product Code	CFR #
DKZ	862.3100
DIS	862.3150
JXM	862.3170
DIO	862.3250
LAF	862.3610
DJG	862.3610
DJG	862.3650
DJR	862.3620
LFG	862.3650
LCM	No regulation number for PCP
DJC	862.3910
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 drugs of abuse using a lateral flow, one step system for the qualitative detection of specific drugs 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 One Step Multiple Drugs of Abuse Assays is intended for the qualitative determination of drugs and their metabolisms In human urine. They are intended for the healthcare professional use including professionals at point-of-care sites.

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

The Wondfo Biotech Co., Ltd. One Step Multiple Drugs of Abuse Assays have similar technological characteristics and performance to the predicate and are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 17 2005

Wondfo Biotech Co. Ltd.
c/o Mr. Howard Mann
Sherbo Associates
8903 Spruce Mill Drive
Yardley, PA 19067

Re: k050024
Trade/Device Name: Multiple Drugs of Abuse Assays
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJR, DJC, DPK, DJG, LCM, LFG
Dated: October 2, 2005
Received: October 5, 2005

Dear Mr. Mann:

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) 276-0484. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, 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

510(k) Number (if known): K050024

Device Name: Multiple Drugs of Abuse Assays

Indications For Use:

One Step Multiple Drugs of Abuse Assays is used for the qualitative determination of the following drugs of abuse in urine:

Product Name	**Cutoff**
Amphetamine (amphetamine)	1000ng/ml
Barbiturate (secobarbital)	300ng/ml
Benzodiazipines (oxazepam)	300ng/ml
Cocaine (benzoylecgonine)	300ng/ml
Methamphetamine (methamphetamine)	1000ng/ml
Morphine (morphine)	300ng/ml
Opiate (morphine)	2000ng/ml
Methadone (methadone)	300ng/ml
Methylenedioxymethamphetamine (methylenedioxymethamphetamine)	500ng/ml
Phencyclidine (phencyclidine)	25ng/ml
Tricyclic antidepressant drugs (nortriptyline)	1000ng/ml
Cannabinoids (tetrahydrocannabinol-COOH)	50ng/ml

The configurations of the One Step Multiple Drugs of Abuse Assays are available in any combination of the above tests. These devices are intended to be used by healthcare professionals only. For in vitro diagnostic use. Measurements obtained by this device are used in the diagnosis and treatment of use or overdose of the drugs listed above.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Nancy Phillips
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050024

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

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

Jerry Phillips

n Sign-Off

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k) K050024