K020869

WORLDWIDE MEDICAL
CORPORATION

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JUN 11 2002

Section D

510(k) Summary
[As required by 21 CFR 807.92]

I. Submitter:

A. Name: Worldwide Medical Corporation

B. Address: 13 Spectrum Pointe Drive, Lake Forest, California 92630

C. Phone and Fax Numbers: Phone: Phone: 949/598-8378
Fax: 949/598-8757

D. Contact Person: Francisco J. Rojas, Ph.D.

II. Date of Preparation of this Summary: March 14, 2002

III. Trade Name: First Check® Home Drug Test for MDMA (Ecstasy)

IV. Common Name: At home drugs of abuse rapid screening test for MDMA (Ecstasy) in urine.

V. Classification Name: Immunoassay for the qualitative detection of drugs of abuse in urine.

VI. The Marketed Products to Which Equivalence is claimed: The First Check® Home Drug Test for MDMA (Ecstasy) that is the subject of this submission is identical to the Applied Biotech SureStep™ MDMA (Ecstasy) Drug Screen Test in terms of use, product design, performance characteristics, materials of construction, and manufacturing process. It is also substantially equivalent to the Phamatech At Home™ Drug Test, and other commercially available drug screening tests that qualitatively measure the presence of target drugs or metabolites by visual color one-step immunoassay technology.

VII. Statement of Intended Use Compared to Other Products: The intended use of the First Check® Home Drug Test for MDMA (Ecstasy) is substantially equivalent to the listed products; it is a preliminary, rapid screening test for the detection of MDMA (Ecstasy) and its metabolites in urine. This product is intended to be the first step in a two step process to provide consumers, including but not limited to concerned parents, with information regarding the presence of MDMA (and its metabolites) in a urine sample. Information regarding the second step, confirmatory testing, is provided.

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VIII. Discussion of Technological Characteristics: The First Check® Home Drug Test for MDMA (Ecstasy), like other commercially available drug screening tests, qualitatively measures the presence or absence of MDMA and its metabolites in urine, using a one step, rapid chromatographic immunoassay which operates under the principle of recognition and formation of specific antibody/target drug/antibody complexes. Examples of predicate devices include the First Check® Home Drug Tests using a single or a multi-drug display. The analytical studies of the identical Applied Biotech SureStep™ MDMA (Ecstasy) Drug Screen Test (K011133) indicate that the drug test reacts specifically with MDMA and its metabolites. The structurally related compounds d- amphetamine, l-amphetamine, d- methamphetamine, and l-methamphetamine at concentrations of 10 to 100 ug/ml produce negative test results. A consumer study using the First Check® Home Drug Test for MDMA (Ecstasy) demonstrates that the test exhibits excellent overall performance in the hands of lay users. The data supports the conclusion that the consumer can use the First Check® Home Drug Test for MDMA (Ecstasy) to obtain immediate, preliminary information regarding the possible use of MDMA. The cutoff concentration for MDMA is 500 ng/ml.

IX. Safety and Effectiveness: Because the First Check® Home Drug Test for MDMA (Ecstasy) is identical to the Applied Biotech SureStep™ MDMA (Ecstasy) Drug Screen Test that is legally marketed under K011133, and because no special skills, training, education, or licensure are required to transfer a dropper level of urine sample into the test card well, there is no issue regarding the safety or effectiveness of the product to perform its intended function, i.e., to screen urine for the presence or absence of MDMA and its metabolite. Because the labeling of the First Check® Home Drug Test for MDMA (Ecstasy) is substantially equivalent to a variety of rapid screening tests currently in commercial distribution, including the Phamatech At Home™ Drug Test, and there have been no reports of consumer inability to follow instructions or interpret results during the twenty-four months in which the First Check® product line has been purchased by the general public and used in quantities exceeding 200,000 tests, it is concluded that the product can be used effectively by the lay user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 11 2002

Francisco J. Rojas, Ph.D.
Chief Scientific Officer
Worldwide Medical Corporation
13 Spectrum Pointe Drive
Lake Forest, CA 92630

Re: k020869
Trade/Device Name: First Check® Home Drug Test for MDMA (Ecstasy)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ
Dated: May 2, 2002
Received: May 3, 2002

Dear Dr. Rojas:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section A

510 (k) Number (if known): K020869

Device Name: First Check® Home Drug Test for MDMA (Ecstasy)

Indications for Use:

The First Check® Home Drug Test for MDMA (Ecstasy) is a screening test for the rapid detection of MDMA and its metabolites in human urine at a cut-off level of 500 ng/ml. The test is intended for consumer use as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of MDMA or its metabolites in a urine sample. Such information is beneficial to consumer efforts to comply with applicable laws and/or societal expectations. Information regarding second step confirmatory testing is provided.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020869

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)