



Section D
510(k) Summary
21 C.F.R. § 807.92

- I. Submitter:
 - A. Name: Worldwide Medical Corporation
 - B. Address: 199 Technology Drive, Suite 150, Irvine, California 92618
 - C. Phone and Fax Numbers: Phone: 949/727-0711
Fax: 949/727-0602
 - D. Contact Person: H. Thad Morris
- II. Date of Preparation of this Summary: November 30, 1999
- III. Trade Name: First Check® Home Drug Test Panel 2
- IV. Common Name: At home drugs of abuse rapid screening test for marijuana and cocaine 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 Panel 2 that is the subject of this submission is identical to the Applied Biotech SureStep™ Drug Screen Multi Test in terms of intended use, product design, performance characteristics, materials of construction, and manufacturing process. It is also substantially equivalent to the Phamatech QuickScreen™ At Home Drug Test and other commercially available drug screening tests which 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 Panel 2 is substantially equivalent to the listed products; it is a preliminary, rapid screening test for the detection of marijuana and cocaine and/or their metabolites in urine. This product is intended to be the first step in a two step process to provide consumers, including concerned parents, with information regarding the presence or absence of these two drugs and/or their metabolites in a urine sample. Information regarding the second step, confirmatory testing, is provided.



- VIII. Discussion of Technological Characteristics: The First Check® Home Drug Test Panel 2, like many commercially available drug screening tests, qualitatively measures the presence or absence of marijuana, and cocaine, and/or their 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. The cut-off concentration for THC is 50ng/mL. The cut-off concentration for COC is 300ng/mL.
- IX. Safety and Effectiveness: Because the First Check® Home Drug Test Panel 2 is identical to the Applied Biotech SureStep™ Drug Screen Multi Test that is legally marketed under K972425, 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 the listed drugs and their metabolites. Because the labeling of the First Check® Home Drug Test Panel 2 is substantially equivalent to a variety of rapid screening tests currently in commercial distribution, including the Phamatech QuickScreen™ 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 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 23 2000

Worldwide Medical Corporation
c/o Mr. Larry R. Pilot
McKenna & Cueno, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006-1108

Re: K994139
Trade Name: First Check[®] Home Drug Test Panel 2
Regulatory Class: II
Product Code: LDJ, DIO
Dated: May 23, 2000
Received: May 23, 2000

Dear Mr. Pilot:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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



SECTION A

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510(k) Number (if known): K994139

Device Name: First Check® Home Drug Test Panel 2

Indications for Use:

The First Check® Home Drug Test Panel 2 is an educational screening test for the rapid detection of marijuana and cocaine and/or their metabolites in human urine at cut-off levels of 50ng/mL and 300ng/mL, respectively. 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 the two drugs listed above in a human 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

OVER-THE-COUNTER USE

Sean Cooper
(Division Sign-Off)
Division of Clinical Lab
510(k) Number K994139