3D Ltd

# 510k Submission for
## DrugScreen Dip Marijuana Test
## SCREENERS Marijuana Test

DEC 27 1999

K992949

**10. Summary of Safety and Effectiveness**

The sponsor Drug Detection Devices Ltd. (6620 Meadowridge Court, Suite A-7, Alpharetta, GA 30005) has had developed and tested under GMP/GLP guidelines a device for the qualitative testing of urine for the presence of Marijuana and its metabolites in a screening format.

The Trade names of the device are SCREENERS Marijuana Test and DrugScreen Dip Marijuana Test, having a designated common name of Cannabinoid Test System and a classification as a class II device per 21 CFR 862.3870. This device is intended for medical/forensic screening of urine.

Drug Detection Devices Marijuana test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a rose-pink color band when the drug is above the detection level of 50 ng/ml. Unbound dye conjugate binds to the reagent in the control zone, producing a rose-pink color band, demonstrating that the reagents and device are functioning correctly.

The final product has been subjected to both in house testing of 261 individual urine samples using both the Syva Emit and GC/MS against the new product. The calculated sensitivity was 0.9801 and specificity was found to be 0.9636 with the accuracy of 97.32%. Subsequently the device was subjected to a broader clinical trial in a NIDA certified laboratory where the calculated sensitivity equaled 0.993, the specificity equaled 1.00 and the calculated accuracy equaled 99.67% when compared to the gold standard of GC/MS. Statistical comparisons of all possible combinations of reference methods to the experimental new device failed to identify any significant difference between the reference method and the Drug Detection Devices method.

Additional information on this submission may be obtained by contacting Bruce Christie, CEO of Drug Detection Devices, Ltd. at 770-886-6226 or by fax at 770-886-7792.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 27 1999

Mr. Bruce Christie
Chief Executive Officer
Drug Detection Devices, Ltd.
6820 Meadowridge Court
Suite A-7
Alpharette, Georgia 30005

Re: K992949
Trade Name: SCREENERS™ Marijuana Test
DrugScreen™ Dip Marijuana Test
Regulatory Class: II
Product Code: LDJ
Dated: November 22, 1999
Received: November 24, 1999

Dear Mr. Christie:

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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 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,

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

**510(k) Number (if Known): To Be Assigned** K992949

**Device Names:** **DrugScreen™ Dip Marijuana Test**
**SCREENERS™ Marijuana Test**

**Indications For Use:**

The Drug Detection Devices Marijuana Test is a rapid, qualitative, competitive binding immunoassay for the determination of Cannabinoids and its metabolites in urine. The test provides only preliminary data, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. This test is not intended to be used in monitoring cannabinoid levels.

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

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992949

**Prescription Use:** ✓ **or** **Over The Counter Use:** _____
**(Per 21 CFR 801.109** **(Optional Format 1-2-96)**