

JUN 24 1999

K990325

510k Submission for  
**QuikStrip DipScan X Multidrug Screening Device**  
Syntron Bioresearch, Inc.

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Revision d 06/17/99 Printed on 06/17/1999

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**18.1 Summary of Safety and Effectiveness**

The sponsor, Syntron Bioresearch, Inc. (2774 Loker Ave. West, Carlsbad, California, 92008), has developed, manufactured, and tested under GMP/GLP guidelines a Strip Holder that will accommodate 2 to 6 of the company's cleared drugs of abuse strips for the qualitative detection in urine of drugs of abuse and their metabolites in a quick, simple, easy to read, screening format. Test strips available for inclusion in the DipScan X are Amphetamine, Methamphetamine, Benzodiazepine, Barbiturates, Cocaine, Marijuana (THC), Opiates (300), and Phencyclidine (PCP).

The trade name of the device is QuikStrip DipScan X Multidrug Screening Device (X is replaced by 2, 3, 4, 5, or 6) having a designated common name of Strip Holder and a classification as a Class II device per FDA. This device is intended for the medical/forensic screening of urine for drugs of abuse.

Syntron's QuikStrip DipScan X Multidrug Screening Device (X is replaced by 2, 3, 4, 5, or 6) consists of two to six (2-6) individual chromatographic absorbent devices 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 for each drug. 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, different for each drug, competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level specified by SAMHSA for GC/MS (Note the cutoff for opiates used in the opiate test strips was 300 ng/ml instead of the new cutoff of 2000ng/ml). Unbound dye conjugate binds to the reagent in the control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly. Each of the test strips in the holder functions independently and is read independently. Test strips available for inclusion in the DipScan X are Amphetamine, Methamphetamine, Benzodiazepine, Barbiturates, Cocaine, Marijuana (THC), Opiates (300), and Phencyclidine (PCP).

In-house testing of QuikStrip DipScan X Multidrug Screening Device yielded no observations of inappropriate reactions or interference between tests.

Additional information on this submission may be obtained by contacting Dr. Cleve W. Laird, President, Drial Consultants, Inc. at 805-522-6223(Ca) or by fax at 805-522-1526.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUL 14 1999

Syntron Bioresearch, Inc.  
c/o Cleve W. Laird, Ph.D.  
President and CEO  
Drial Consultants, Inc.  
1420 Los Angeles Ave. Suite 201  
Simi Valley, California 93065

Re: K990325  
Trade Name: QuikStrip DipScan X Multidrug Screening Device  
Regulatory Class: II  
Product Code: DKZ, DJC, DIS, JXM, LDJ, DIO, LCM, DJG  
Dated: May 11, 1999  
Received: May 13, 1999

Dear Dr. Laird:

This letter corrects our substantially equivalent letter of June 24, 1999 regarding the incorrect trade name, QuikScan Drug Test X Multidrug Screening Device. Your June 7, 1999, correspondence incorrectly identified QuikScan DipScan X Multidrug Screening Device as the trade name.

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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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

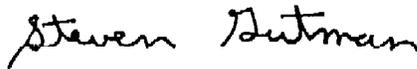
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 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): K990325

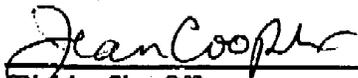
Device Name: QuikStrip DipScan X Multidrug Screening Device

**Indications For Use:**

Syntron's QuikStrip DipScan X Multidrug Screening Device (the X is replaced by 2, 3, 4, 5, or 6) is a holder for up to six rapid, qualitative, competitive binding immunoassay strips for the detection of drugs of abuse in urine at the SAMHSA designated GC/MS cutoff levels. The test strips available for inclusion in the DipScan are Amphetamine, Methamphetamine, Benzodiazepine, Barbiturates, Cocaine, Marijuana (THC), Opiates, and Phencyclidine (PCP). The tests provide only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrophotometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated<sup>6</sup>. Syntron's QuikStrip DipScan X Multidrug Screening Device is not intended to monitor drug levels, but only to screen urines for the presence of specific drugs of abuse and their metabolites.

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

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

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K990325

Prescription Use:  \_\_\_\_\_  
(Per 21 CFR 801.109)

or

Over The Counter Use: \_\_\_\_\_  
(Optional Format 1-2-96)